Agenda Item 7

Miscellaneous Consumer Issues and Articles in the Media

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication and Public Education Committee

Subject: Miscellaneous Consumer Issues and Articles in the Media

---

These items are provided for the Communication and Public Education Committee (Committee) relating to the pharmaceutical industry and consumer interest. During this meeting, the Committee can review and discuss these items.

1. Direct-to-Consumer Marketing

   - Sacramento Bee article dated August 2007 entitled "There's A Pill For That"
   - Federal Register Notice dated August 22, 2007 announcing an opportunity for public comment on a proposed collection of certain information
   - LA Times article dated August 6, 2007 entitled "Next Step: Create The Demand"

2. Miscellaneous Consumer Issues and other articles in the media

   - Letter from Stanley E. Miller dated June 28, 2007
   - Article posted on kaisernetwork.org dated August 6, 2007
   - LA Times article dated August 6, 2007 entitled "Doctor, just a little something for you"
   - LA Times article dated August 6, 2007 entitled "In short, marking works"
   - LA Times article dated August 6, 2007 entitled "And now, a push for change"
   - LA Times article dated August 6, 2007 entitled "Under the influence"
   - LA Times article dated August 6, 2007 entitled "From funding to findings"
   - Article posted on kaisernetwork.org dated August 8, 2007 entitled "Use of Generic Prescription Drugs Increasing as Patents Expire on Blockbuster Medications; Trend Expected to Reduce Overall Drug Spending
   - Article posted on DrugTopics.com dated July 9, 2007 entitled "FDA hears of problems with Med Guides"
   - Notice posted on National Public Radio Web site dated July 17, 2007 entitled "Marketplace Report: Drug Guarantees"
   - Article from The New York Times dated July 14, 2007 entitled "Pricing Pills by the Results"

- Article from The Sacramento Bee dated June 25, 2007 entitled "AMA wants probe of store clinics"
- Article from The New York Times dated July 3, 2007 entitled "Keeping Patients' Details Private, Even From Kin"
- Article from AARP Bulletin dated July-August 2007 entitled "The More Things Change..."
- FDA News Release dated June 21, 2007 entitled "FDA Clears Computerized Medication Box for U.S. Market
- Article posted on americaspharmacist.net dated June 2007 entitled "FDA Change on RPh Drug Class?"
- Article posted on DrugTopics.com dated August 24, 2007 entitled "Verispan takes a past and future look at drug market"
- FDA News Release dated June 22, 2007 entitled "FDA Issues Dietary Supplements Final Rule"

Items Relating to Direct-to-Consumer Marketing

08/07 Sacto Bee

There's a pill for that

FDA needs ample ability to crack down on drug companies' consumer advertising

Do you have feelings of inadequacy? Do you suffer from shyness?

If you answered yes to either of those questions, ask your doctor or pharmacist about the benefits of ... tequila.

At MySpace.com, you can see this cheeky tequila parody of ubiquitous drug ads, complete with a rapid-fire recitation of side effects that range from dizziness, nausea, incarceration and table dancing to the desire to play naked Twister and sing all-night karaoke.

The satirical video posted by Jonathan in Colorado points directly to a cultural and commercial phenomenon at work in our living rooms and on Capitol Hill. The big drug companies have been increasing their promotional spending: $11.4 billion in 1996 to $29.9 billion in 2005. Those ads we all recognize ("ask your doctor about...") are known as "direct-to-consumer" or DTC advertising. The pharmaceutical companies' spending on them rose 330 percent in that 1996-2005 period. (DTC drug ad spending was $5.61 billion in 2006.)

The New England Journal of Medicine published an article this month detailing the numbers and documenting the trends. Evidence suggests that the direct-to-consumer advertising increases sales, averts underuse of medicines and leads to potential overuse, the article said.

After the journal article appeared, the federal Food and Drug Administration said it would study what sounds like the obvious: whether the upbeat ads leave people with a positive impression that distracts them from audio warnings about side effects. But if the research gives the FDA more oomph in its enforcement power over problematic advertising, the study will be worth it. (The journal said the FDA sent only 21 citations regarding drug-advertising regulations in 2006, compared with 142 in 1997.)

On Capitol Hill, there is hope that in the next few weeks the House and Senate will agree on language to give the FDA more tools for enforcement. But a major hammer – a moratorium under which companies introducing a new drug couldn't advertise it for two years – got stripped from FDA legislation. That would have allowed time to see if safety issues arose. But that's gone.

For now, advocates at Consumers Union, publisher of Consumer Reports and one of the main groups pushing for more oversight, rightly want to see Congress help the FDA speed its process of enforcing advertising regulations. If regulators find a problem with a drug, they shouldn't have to pick their way through a lengthy legal process to cancel a misleading drug ad.

The way it works now, by the time the FDA gets its message across, the drug company has often moved on with a new ad, singing the benefits of yet another drug we should ask our doctors about.

Published

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0321]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study of consumer evaluations of variations in communicating risk information in direct-to-consumer (DTC) prescription drug broadcast advertisements.

DATES: Submit written or electronic comments on the collection of information by October 22, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in DTC Prescription Drug Broadcast Advertisements

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act.

FDA regulations require that advertisements that make claims about a prescription drug include a "fair balance" of information about the benefits and risks of advertised products, in terms of both content and presentation. Ads can present information in ways that can optimize or skew the relative balance of risks and benefits. Both healthcare providers and consumers have expressed concerns to FDA about the effectiveness of its regulation of manufacturers' DTC prescription drug advertising, especially as it relates to assuring balanced communication of risks compared with benefits.

One characteristic of DTC television broadcast ads is the use of compelling visuals. Many assert that the visuals present during the product risk presentation are virtually always positive in tone and often depict product benefits. A consistently raised question is whether advertising visuals of benefits interferes with consumers' understanding and processing of the risk information in the ad's audio or text.

The purpose of the proposed study is, in part, to determine whether the use of competing, compelling visual information about potential drug benefits interferes with viewers' processing and comprehension of risk information about drugs in DTC advertising or with their cognitive representations of the drugs. Positive visual images could influence the processing of risk-related information and the final representation of the advertised drug in multiple ways. First, compelling visuals could simply distract consumers from carefully considering and encoding the risk information. To the extent that compelling visuals cause them to attend to or to process risk information less, participants exposed to risk information with simultaneous compelling positive visuals should recall fewer risks (and perhaps fewer benefits) than do participants exposed to the risk information without the positive visuals. Second, compelling visuals may affect the way consumers think about the brand, specifically their attitudes toward the advertised brand (Ref. 1). An attitude is simply an association between an object and a degree of positivity or negativity. Attitudes can be important determinants of behavior; in some contexts, they may have more impact than factual information. That is, under many circumstances, people rely much less on facts that they know, such as the number of risks associated with ibuprofen, and much more on general feelings they have, such as strong positivity toward Advil. Compelling visuals in DTC advertising have the potential to lead a consumer to form a positive opinion of a drug for no other reason than that it is presented in the same context as positive images.

Another purpose of the present study is to examine the role of textual elements in the processing of risk information. Sponsors often place superimposed text ("supers") onto the screen to clarify spoken information or to provide extra information that is not included in the audio. For example, information such as adequate provision

statements ("See our ad in...") and limits to indication statements may appear. This text potentially has the power to distract viewers from the more important audio information, although only if viewers pay attention to the text. Likewise, providing verbatim repetition of the audio risks in text format may facilitate the processing of the risks. We will examine the added distraction or facilitation of the text in the present study in addition to the role of visual information.

We have limited data about how consumers perceive risk and benefit information in DTC broadcast ads as a function of exposure to different content and presentations. Therefore, we do not fully understand the influence of visual and textual factors on the conveyance of a balanced picture of the product.

This study will investigate the impact of visual distraction and the interplay of different sensory modalities (verbal, visual) used to present risk and benefit information during a television prescription drug advertisement. Data from this study will provide useful information to help improve how broadcast ads present a prescription drug's risks and benefits.

Design: This study will employ a between-subjects crossed 3 x 3 factorial design with two independent variables. The first independent variable represents the consistency of the disclosure of risk information between the audio and text (superimposed text, or "supers") portions of television ads. It will have three conditions: "Reinforcing" text, "competing" text, and a "control" condition with no text. We define "reinforcing" text as a verbatim repetition of the audio risk; "competing" text will include contextual information for understanding usage and will not contain risk or benefit information. The second independent variable is the consistency of background visuals with the audio presentation of risk information. It will have three conditions: Consistent visuals, neutral visuals, and inconsistent visuals.

Participants: Data will be collected using a mall-intercept protocol in multiple locations across the continental United States. Consumers over the age of 40 will be screened and recruited by the contractor to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all selected participants must speak English as their primary language and have reading glasses available as needed. In addition, due to the nature of one of our measures requiring a set of neutral stimuli, which we have designated as Chinese characters, it will be necessary for us to eliminate individuals who can read Chinese.

We chose to limit our investigation to one disease condition: High blood pressure. High blood pressure remains a significant public health concern but because there is little DTC promotion for high blood pressure treatment, participants should be less familiar with television ads for these types of drugs, reducing the potential influence of prior experience. Further, many older people have or are at risk for high blood pressure, which should facilitate recruitment.

Procedure: Participants will be shown one DTC ad for high blood pressure. Then a structured interview will be conducted with each participant to examine a number of important perceptions about the advertised product, including perceived riskiness of the drug, comprehension of risk and benefit information, perceived balance of risk and benefit information, and attitudes toward the drug product.

Because attitudes are often a strong determinant of behavior, we will investigate this dependent variable in two ways. First, we will use an implicit measure to determine whether participants have an overall positive or negative attitude toward the drug product. Implicit measurement of attitudes is a relatively new but well-validated process for understanding people's feelings toward particular entities (Ref. 1). The Affect Misattribution Procedure, in which participants are asked to respond to neutral characters (such as Chinese symbols) after viewing pictures of the object of interest, has been validated as an unobtrusive way to attain these measures. We expect attitudes toward the drug product to vary depending on each participant's experimental condition (i.e., whether they have adequately processed the risk information or not). This implicit method will be conducted after participants see the broadcast ad but before they are asked any other questions that might influence their responses. Second, we will assess attitudes and behavioral intentions using more traditional explicit measures, i.e. asking participants directly. Including both types of measures will allow us to further validate these measures in a DTC context.

Finally, demographic and health care utilization information will be collected. The entire procedure is expected to last approximately 15 minutes. A total of 1,020 interviews will be completed. This will be a one-time (rather than annual) information collection.

FDA estimates the burden of this collection of information as follows:

FDA estimates that 2,000 individuals will need to be screened to obtain a respondent sample of 1,020 for the study. The screener is expected to take 30 seconds, for a total screener burden of 16 hours. The 1,020 respondents in the study will then be asked to respond to a series of questions about the advertisement. The ad viewing and questionnaire are expected to take 15 minutes, for a study burden of 255 hours. The estimated total burden for this data collection effort is 271 hours. The respondent burden is provided in table 1 of this document:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,000 (screener)	1	2,000	.008	16
1,020 (study)	1	1,020	.25	255
Total				271

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following reference has been placed on public display in the Division of Dockets Management (see **ADDRESSES**), and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Payne, B.K., C.M. Cheng, O. Govorun, et al., "An Inkblot for Attitudes: Affect Misattribution as Implicit Measurement," *Journal of Personality and Social Psychology*, vol. 89 (3), pp. 277–293, 2005.

Dated: August 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–16603 Filed 8–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel, T35 Short Term Institutionals Research Training.

Date: September 20, 2007.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Stanley C. Oaks, PhD, Scientific Review Administrator, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd—MSC 7180, Bethesda, MD 20892–7180, 301–496–8683, *so14s@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel, Diseases of the Vestibular System.

Date: September 24, 2007.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Christine A. Livingston, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496–8683, *livingsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4101 Filed 8–21–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Independent Evaluation of the Community Mental Health Services Block Grant Program—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), the Center for Mental Health Services (CMHS) administers the Community Mental Health Services Block Grant (CMHS BG). The Community Mental Health Services Block Grant was funded by Congress to develop community-based systems of care for adults with serious mental illness (SMI) and children with severe emotional disorders (SED), and has been the largest Federal program dedicated to improving community mental health services. States have latitude in determining how to spend their funds to support services for adults with SMI and children with SED. The only requirements outlined in the authorizing legislation for State receipt of CMHS BG funds are provisions to increase children's services, create a State mental health planning council, and to develop a State mental health plan to be submitted to the Secretary of Health and Human Services (HHS). The State mental health planning council is to comprise various State constituents including providers, administrators, and mental health services consumers. Each State plan must:

- Provide for the establishment and implementation of an organized community-based system of care for individuals with mental illness.
- Estimate the incidence and prevalence of adults with SMI and children with SED within the State.
- Provide for a system of integrated services appropriate for the multiple needs of children.
- Provide for outreach to and services for rural and homeless populations.
- Describe the financial and other resources necessary to implement the plan and describe how the CMHS BG funds are to be spent.

In addition, Congress included a maintenance-of-effort (MOE) requirement that a State's expenditures for community mental health services be no less than the average spent in the two preceding fiscal years.

The CMHS BG received an adequate rating on the OMB PART in 2003. Clearly in the follow up period to that assessment, one of the critical areas that must be addressed is the expectation that an independent and objective evaluation of the program is to be carried out initially and at regular intervals. In addition, the program evaluation has been designed to be of high quality, sufficient scope and unbiased (with appropriate documentation for each of these elements). In fact it is in addressing an evaluation of the program that critical elements of accountability and program performance are also identified and initially assessed. The rigor of the evaluation is seen in how it addresses the effectiveness of the program's impact with regard to its mission and long term goals. By legislative design the CMHS BG Program has previously focused on legislative compliance. Now it addresses the impact of the program nationally, over time, with a view to coming to terms with identified program deficiencies and the corresponding impact of proposed changes.

In this evaluation, a multi-method evaluation approach is being used to examine Federal and State performance with regard to the CMHS BG and its identified goals. This approach emphasizes a qualitative and quantitative examination of both the CMHS BG *process* (e.g., activities and outputs in the logic model) and system-level *outcomes* whereby Federal and State stakeholder perspectives on the CMHS BG, as captured through semi-structured interviews and surveys, are

Display Date 8-21-07
Publication Date 8-22-07
Certifier L. CLAWSON
DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0321]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study of consumer evaluations of variations in communicating risk information in direct-to-consumer (DTC) prescription drug broadcast advertisements.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**]

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets

oc07205

2007N-0321

N1

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in DTC Prescription Drug Broadcast Advertisements

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act.

FDA regulations require that advertisements that make claims about a prescription drug include a "fair balance" of information about the benefits and risks of advertised products, in terms of both content and presentation. Ads can present information in ways that can optimize or skew the relative balance of risks and benefits. Both healthcare providers and consumers have expressed concerns to FDA about the effectiveness of its regulation of manufacturers' DTC prescription drug advertising, especially as it relates to assuring balanced communication of risks compared with benefits.

One characteristic of DTC television broadcast ads is the use of compelling visuals. Many assert that the visuals present during the product risk presentation are virtually always positive in tone and often depict product benefits. A consistently raised question is whether advertising visuals of benefits interferes with consumers' understanding and processing of the risk information in the ad's audio or text.

The purpose of the proposed study is, in part, to determine whether the use of competing, compelling visual information about potential drug benefits interferes with viewers' processing and comprehension of risk information about drugs in DTC advertising or with their cognitive representations of the drugs. Positive visual images could influence the processing of risk-related information and the final representation of the advertised drug in multiple ways. First, compelling visuals could simply distract consumers from carefully considering and encoding the risk information. To the extent that compelling visuals cause them to attend to or to process risk information less, participants exposed to risk information with simultaneous compelling positive visuals should recall fewer risks (and perhaps fewer benefits) than do participants exposed to the risk information without the positive visuals. Second, compelling visuals may affect the way consumers think about the brand, specifically their attitudes toward the advertised brand (Ref. 1). An attitude is simply an association between an object and a degree of positivity or negativity. Attitudes can be important determinants of behavior; in some contexts, they may have more impact than factual information. That is, under many circumstances, people rely much less on facts that they know, such as the number of risks associated with ibuprofen, and much more on general feelings they have, such as strong positivity toward Advil. Compelling visuals in DTC advertising have the potential to lead a consumer to form a positive opinion of a drug for no other reason than that it is presented in the same context as positive images.

Another purpose of the present study is to examine the role of textual elements in the processing of risk information. Sponsors often place superimposed text ("supers") onto the screen to clarify spoken information or

to provide extra information that is not included in the audio. For example, information such as adequate provision statements ("See our ad in...") and limits to indication statements may appear. This text potentially has the power to distract viewers from the more important audio information, although only if viewers pay attention to the text. Likewise, providing verbatim repetition of the audio risks in text format may facilitate the processing of the risks. We will examine the added distraction or facilitation of the text in the present study in addition to the role of visual information.

We have limited data about how consumers perceive risk and benefit information in DTC broadcast ads as a function of exposure to different content and presentations. Therefore, we do not fully understand the influence of visual and textual factors on the conveyance of a balanced picture of the product.

This study will investigate the impact of visual distraction and the interplay of different sensory modalities (verbal, visual) used to present risk and benefit information during a television prescription drug advertisement. Data from this study will provide useful information to help improve how broadcast ads present a prescription drug's risks and benefits.

Design: This study will employ a between-subjects crossed 3 x 3 factorial design with two independent variables. The first independent variable represents the consistency of the disclosure of risk information between the audio and text (superimposed text, or "supers") portions of television ads. It will have three conditions: "Reinforcing" text, "competing" text, and a "control" condition with no text. We define "reinforcing" text as a verbatim repetition of the audio risk; "competing" text will include contextual information for understanding usage and will not contain risk or benefit

information. The second independent variable is the consistency of background visuals with the audio presentation of risk information. It will have three conditions: Consistent visuals, neutral visuals, and inconsistent visuals.

Participants: Data will be collected using a mall-intercept protocol in multiple locations across the continental United States. Consumers over the age of 40 will be screened and recruited by the contractor to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all selected participants must speak English as their primary language and have reading glasses available as needed. In addition, due to the nature of one of our measures requiring a set of neutral stimuli, which we have designated as Chinese characters, it will be necessary for us to eliminate individuals who can read Chinese.

We chose to limit our investigation to one disease condition: High blood pressure. High blood pressure remains a significant public health concern but because there is little DTC promotion for high blood pressure treatment, participants should be less familiar with television ads for these types of drugs, reducing the potential influence of prior experience. Further, many older people have or are at risk for high blood pressure, which should facilitate recruitment.

Procedure: Participants will be shown one DTC ad for high blood pressure. Then a structured interview will be conducted with each participant to examine a number of important perceptions about the advertised product, including perceived riskiness of the drug, comprehension of risk and benefit information, perceived balance of risk and benefit information, and attitudes toward the drug product.

Because attitudes are often a strong determinant of behavior, we will investigate this dependent variable in two ways. First, we will use an implicit measure to determine whether participants have an overall positive or negative attitude toward the drug product. Implicit measurement of attitudes is a relatively new but well-validated process for understanding people's feelings toward particular entities (Ref. 1). The Affect Misattribution Procedure, in which participants are asked to respond to neutral characters (such as Chinese symbols) after viewing pictures of the object of interest, has been validated as an unobtrusive way to attain these measures. We expect attitudes toward the drug product to vary depending on each participant's experimental condition (i.e., whether they have adequately processed the risk information or not). This implicit method will be conducted after participants see the broadcast ad but before they are asked any other questions that might influence their responses. Second, we will assess attitudes and behavioral intentions using more traditional explicit measures, i.e. asking participants directly. Including both types of measures will allow us to further validate these measures in a DTC context.

Finally, demographic and health care utilization information will be collected. The entire procedure is expected to last approximately 15 minutes. A total of 1,020 interviews will be completed. This will be a one-time (rather than annual) information collection.

FDA estimates the burden of this collection of information as follows:

FDA estimates that 2,000 individuals will need to be screened to obtain a respondent sample of 1,020 for the study. The screener is expected to take 30 seconds, for a total screener burden of 16 hours. The 1,020 respondents in the study will then be asked to respond to a series of questions about the

advertisement. The ad viewing and questionnaire are expected to take 15 minutes, for a study burden of 255 hours. The estimated total burden for this data collection effort is 271 hours. The respondent burden is provided in table 1 of this document:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,000 (screener)	1	2,000	.008	16
1,020 (study)	1	1,020	.25	255
Total				271

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following reference has been placed on public display in the Division of Dockets Management (see **ADDRESSES**), and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Payne, B.K., C.M. Cheng, O. Govorun, et al., "An Inkblot for Attitudes: Affect Misattribution as Implicit Measurement," *Journal of Personality and Social Psychology*, vol. 89 (3), pp. 277–293, 2005.

Dated: 8/16/07
August 16, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

BILLING CODE 4160–01–S

Los Angeles Times
latimes.com

http://www.latimes.com/features/health/la-he-sellingthepatient6aug06,1,3130043.story?coll=la-headlines-health&ctrack=7&cset=true
From the Los Angeles Times

SELLING THE PATIENT

Next step: Create the demand

Direct, emotional ads for prescription drugs are everywhere. But they're just one way to get to the consumer.

By Melissa Healy
Los Angeles Times Staff Writer

August 6, 2007

WITH vast and profitable markets up for grabs, drug companies are aggressively reaching beyond doctors and taking their marketing messages directly to consumers.

Some of their promotional strategies have become hard to miss. Nightly news broadcasts -- a beloved habit for aging Americans -- are brought to you by the makers of prescription medications for high cholesterol, arthritis, Alzheimer's disease and erectile dysfunction; an Internet search for a specific symptom, or a visit to any popular health site, will bring up sponsored links and blinking ads for at least one prescription medication used to treat that symptom; fans of NASCAR see Viagra advertised every time No. 6 Mark Martin's car rounds the track. And women paging through a magazine for tips on reducing clutter can scarcely avoid the faces and personal stories of actresses who are managing their depression, osteoporosis or hot flashes with a brand-name pill.

In 1997, the FDA loosened regulations governing the advertisement of prescription medications directly to consumers. The change set off explosive growth in marketing aimed at a general audience long on interest and -- compared with physicians -- short on professional skepticism. Today, drug makers spend roughly $5 billion a year to run advertising campaigns that use many of the same appeals that marketers use to sell breakfast cereal and toothpaste.

A study published in the Annals of Family Medicine's January-February issue analyzed the messages of 38 advertisements then running during prime-time TV and found that 95% used emotional appeals to sell the medication, often framing prescription-drug use as a means to regain lost control over some aspect of life. None mentioned lifestyle change as an alternative to product use, although roughly 1 in 5 advertisements suggested it might be a useful complement to the drug. One in 4 described the causes of the disease the advertised drug treats, who is at risk for it or how frequently the condition occurs in the population. The study's authors, led by UCLA researcher Dominick L. Frosh, suggested that without such information, consumers would have little reason to see prescription medication as a solution that involves risks as well as possible benefits.

In all, 58% portrayed the advertised drug as a medical breakthrough -- a pharmaceutical twist on Madison Avenue's "new and improved" message.

"It is time to ban direct-to-consumer advertising of prescription drugs," wrote Dr. Kurt Stange, editor of the Annals, in an accompanying editorial. The advertisements consumers see "distort the relationship between patients and clinicians. [They] manipulate a patient's agenda and steal precious time away from an evidence-based primary care clinician agenda that is attempting to promote healthy behavior, screen for early-stage treatable disease and address mental health."

Even after 23 major pharmaceutical companies agreed to a new slate of voluntary guidelines limiting their advertising, Stange wasn't buying it. Self-monitoring, he wrote, "is not working . . . and cannot realistically be

expected to work."

PhRMA, the drug manufacturers' industry group, says direct-to-consumer advertising empowers patients to take an active role in their healthcare and spurs them to discuss symptoms, diseases and treatment options with their doctors that might otherwise go unraised. The industry group frequently cites a 2002 survey of consumers that found that 43% were spurred by a prescription-drug ad to look for more information about the drug or their health.

Although direct-to-consumer advertising has spurred the most political and professional debate, it is only the most visible means of prescription-drug marketing aimed at the consumer. To build markets and encourage consumer loyalty to their products, drug makers have invested heavily in a tactic known to public relations professionals as "third-party marketing." Through voices, groups and activities that seem independent of them -- but frequently are not -- drug companies have found another way to get their messages to consumers.

'Third-party' approach

ACCORDING to an article published in the British Medical Journal in 2003, the top five public relations firms specializing in healthcare earned $300 million in 2002. These firms "are expert at 'third-party technique' -- helping the drug industry separate the message from what could be seen as a self-interested messenger," wrote authors Bob Burton and Andy Rowell.

Last October, a commentary in the New England Journal of Medicine detailed one little-noticed third-party marketing venture. Underwritten by Eli Lilly, the campaign was designed to increase the use in hospitals of a drug commercially known as Xigris, for the treatment of sepsis, or blood poisoning. A preliminary study had suggested some safety concerns with Xigris, and an FDA advisory panel had urged more thorough study of the drug before its approval. But in 2001, the FDA approved its entry into the market. The controversy appeared to sap first-year sales of Xigris, which fell short of Lilly's expectations.

Lilly's response was to secure the services of a small public relations firm, New York-based Belsito and Co. Belsito would begin spreading the word to physicians and media outlets specializing in medical news that Xigris was being rationed and that physicians were being "systematically forced," because of the drug's high cost, to decide which patients would live and which would die. A $1.8-million educational grant from Lilly would fund the creation of a group of physicians and bioethicists -- named the "Values, Ethics and Rationing of Care Task Force" -- to study this rationing and its ethical implications. And a Surviving Sepsis campaign was launched "in theory to raise awareness of severe sepsis and generate momentum toward the development of treatment guidelines," wrote Dr. Peter Q. Eichacker and two fellow investigators based at the National Institutes of Health, in the NEJM.

Lilly's financial inspiration of the campaign aimed at physicians, patients groups and the media was not apparent to many of the audiences reached. But its effect was quite clear, concluded a case study of the campaign done by the Council of Public Relations Firms: Sales of Xigris "have begun to trend upwards. Through the first quarter of 2004, Xigris sales were up 36%."

In such campaigns, public relations companies operate as off-site extensions of a drug company's marketing department. But sometimes, the relationship of a drug company and a third-party voice is more complex. The tie between patient-advocacy groups and drug companies is a good example.

Drug makers richly support the nation's proliferating patient-advocacy groups, and only a handful of the charitable organizations refuse the sponsorship of pharmaceutical firms, says Georgetown University's Dr. Adriane Fugh-Berman, who has studied these ties. That link presents rich marketing opportunities for corporate sponsors with an interest in reaching the patients the organizations advise and represent, Fugh-Berman says. But it also raises real questions about the independence of patients groups, she adds.

In marketing trade publications, the value of patients' groups is widely touted. As friends and allies to potential customers, groups dedicated to patients who suffer from a specific condition can be powerful marketing tools. Patients seek information and emotional support from these groups, and trust them as an unbiased source of

advice. Groups that empower patients to seek treatment are eager to foster awareness of their disease and, in the process, expand their membership. When they are successful, patients groups have a natural market-building effect.

But drug makers have the deep pockets, and patients groups -- until they're very large and well-established -- are constantly scrambling for money. As a result, according to those calling for reform, the relationship is not always an alliance of equals.

"There's an inherent conflict of interest," says Merrill Goozner, editor of Integrity in Science, a publication of the Washington-based watchdog group the Center for Science in the Public Interest. "The question becomes, 'Are you doing the best for the patients you represent, or are you doing the best for your sponsors?' "

Goozner says that patient-advocacy groups are especially vulnerable to carrying drug companies' messages, untempered by skepticism, directly to their members. "They're desperate" for a cure or treatment, he says. "And no one likes to be told that this latest breakthrough is not all it's been cracked up to be," especially when it's being pushed by a company that's been generous with funding, he adds.

Last October, the magazine New Scientist published a survey gauging the dependence of randomly selected U.S. patients' groups on drug manufacturers. Combing through the tax returns, annual reports and voluntary disclosures of 29 nonprofit patient-advocacy groups, the publication found that most accepted financial backing by companies developing or producing drugs used to treat patients supported by the group. In some groups, such as the American Heart Assn., the drug makers' financial backing was huge ($23 million in 2005) but represented a small portion (4%) of revenue. For seven groups, donations from interested drug companies represented more than one-fifth of revenue. The Depression and Bipolar Support Alliance said it received more than half of its 2005 funding from the drug industry, and the Colorectal Cancer Coalition got 81% of its funding from drug makers.

New Scientist's probe found that some donations appeared directly tied to marketing interests. In 2003 and 2004, when the drug giant Pfizer was developing a drug to treat restless leg syndrome, it was a major donor to the Restless Legs Syndrome Foundation. But in 2005, after Pfizer announced it had abandoned development of the potential drug, its donations to the patient group dried up.

Many of the best-known groups, including the Alzheimer's Assn., American Cancer Society and American Diabetes Assn., typically have a board of physicians who vet the scientific accuracy of the information they provide to patients. And most solicit "unrestricted" grants that allow them freedom to use the drug makers' donations as they see fit.

But even large groups often provide a gateway to the products of corporate sponsors, say those who have surveyed them. Many list FDA-approved medicines available to treat the disorder that is their focus and provide Web links that lead patients directly to marketing sites. And many offer their corporate sponsors access to their members, a potential gold mine of direct-marketing opportunity.

The corporate-donor pitch posted on the website of the national infertility patient group, Resolve, is typical of many patient groups. "Whether you become a site sponsor, a resource partner, or a sponsor of Resolve's chats, [the group's website] is the ideal place for your company to market its products and services to thousands of men and women across the country," the appeal states. Among the benefits the group lists for becoming a member of the group's "Corporate Council" are access to data on utilization of the group's programs and services and "the opportunity to establish topics and sponsor special briefings for patients, the medical community and public policy makers." Serono and Organon, both makers of prescription medication used to treat infertility, are among the group's corporate sponsors.

Patient groups also mobilize patients -- sometimes armies of them -- to push for coverage of prescription drugs by insurance companies and states' Medicare and Medicaid agencies. To pharmaceutical companies, this can make or break the market prospects for a new drug because 80 million Americans -- among them, the heaviest prescription-drug users -- receive healthcare coverage through Medicare and Medicaid, and roughly 155 million have

prescription drug coverage through private insurance companies.

Strength in numbers

WHEN insurers balk at reimbursing patients for new prescription medications, these groups typically swing into action, rallying sufferers to appear before public and consumer panels, contact lawmakers, and provide media outlets a human face to attach to a cause. Infertility patients mobilized by Resolve, for instance, have been extremely effective in extending states' insurance coverage of infertility treatments. Groups such as the Depression and Bipolar Support Alliance have fielded experts and patients who have done the same for psychiatric conditions. And a wide range of patient groups, most with substantial backing from the makers of erectile dysfunction drugs, have mounted successful campaigns to get wary insurers to cover drugs such as Levitra, Viagra and Cialis.

Miscellaneous Consumer Issues and other articles in the Media

Public Ed

June 28, 2007

California State Board of Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834

Gentlemen:

At the suggestion of the U.S. FDA, I am forwarding a copy of my letter to them.

There is something not quite right about prescription drugs not identifying the manufacturer and the country of origin. Other ingested items, like food, seem to at least identify the county of origin. Is this not a requirement in the pharmaceutical industry in California? Are individual pharmacies at their discretion on this? I would be interested in your requirements on this.

Thank you,

Stanley Miller

Stanley E. Miller
22685 Barlovento
Mission Viejo, CA 92692

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services

Food and Drug Administration
Rockville, MD 20857

June 12, 2007

Stanley Miller
22685 Barlovento
Mission, Viejo, CA 92692

Dear Mr. Miller:

Thank you for writing to the Food and Drug Administration (FDA). This is in response to your letter dated May 15, 2007, regarding the manufacturing information not found on the pharmacy label of the prescription drug you received from Longs Pharmacy. Your letter was forwarded to my office in the Center for Drug Evaluation and Research (CDER) for response.

Your points are well taken as your complaint is not the first we have received. Unfortunately, we do not have any jurisdiction in this matter. As you may know, the FDA is a Federal Agency responsible for ensuring that drug products are safe and effective for use as directed in the labeling. Laws governing what is found on your prescription drug vial label are considered the by the FDA to be the practice of pharmacy. The Federal Food, Drug, and Cosmetic Act does not authorize the FDA to regulate the practice of pharmacy. State licensing boards set these standards. If you still have questions concerning information that is found on pharmacy labels, you may wish to contact the California State Board of Pharmacy to discuss your concerns or to file a complaint.

I hope this information is helpful. If I can provide further assistance please do not hesitate to contact me.

Sincerely,

Donald Dobbs
Consumer Safety Officer
Division of Drug Information (HFD-240)
Office of Training and Communications
Center for Drug Evaluation and Research

May 15, 2007

U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Gentlemen:

My wife was recently given a prescription by here doctor for Azithromycin. We had this prescription filled (copy attached). Not only was the price totally obscene, but no where on the package does it indicate which company made the drug or in which country. If I go to the grocery store and buy blue berries, it says clearly on the package that the berries came from Chile. If I go the Nordstrom's and buy clothes, the clothes clearly state they were made in Outer Mongolia. The only indication on the drug package is that it is *distributed* by Greenstone Ltd., but does not state who made the drug or where. There is something wrong with this picture. We are to ingest these pills but don't have a clue who made them or where. Is Greenstone not in compliance with U.S. law? Please advise.

Thank you,

Stanley Miller
22685 Barlovento
Mission Viejo, CA 92692

Attachment

PATIENT PRESCRIPTION INFORMATION

MILLER, BEVERLY

AZITHROMYCIN 250 MG TABLET (GREENSTONE LTD.)

AZITHROMYCIN 1132 (Adult)

Rx#: 1442078 COPAY: $27.48

Longs Drugs

27750 SANTA MARGARITA PARKWAY
MISSION VIEJO, CA 92691

COMMON USE(S) FOR THIS DRUG: Azithromycin is an antibiotic (macrolide-type) used to treat a wide variety of bacterial infections. It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

HOW TO TAKE THIS MEDICATION: Take this medication by mouth with or without food, usually once a day, or as directed by your doctor. You may take this medication with food if stomach upset occurs. Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at the same time each day. Continue to take this medication until the full prescribed amount is finished even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection. Antacids may decrease the absorption of azithromycin. If you take an antacid, wait at least 2 hours after taking this medication. Inform your doctor if your condition persists or worsens.

POSSIBLE SIDE EFFECTS: Stomach upset, diarrhea/loose stools, nausea, vomiting, or stomach/abdominal pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: hearing loss. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: dark urine, persistent nausea/vomiting, severe stomach/abdominal pain, yellowing of the eyes or skin. Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/slow/irregular heartbeat. This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to a resistant bacteria. This condition may occur weeks after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, or blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. An allergic reaction to this medication may return even if you stop the drug. If you have an allergic reaction, continue to watch for any of the above symptoms for several days after your last dose. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: Before taking azithromycin, tell your doctor or pharmacist if you are allergic to it; or to other macrolide antibiotics such as erythromycin, clarithromycin; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, a certain heart problem (QT prolongation in the EKG). This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. This drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: See also the How to Use section. Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: aluminum- and magnesium-containing antacids, digoxin, live bacterial vaccines, lovastatin, nelfinavir, warfarin. This medication may decrease the effectiveness of combination-type birth control pills. This can result in pregnancy. You may need to use an additional form of reliable birth control while using this medication. Consult your doctor or pharmacist for details. Other drugs besides azithromycin which may affect the heart rhythm (QTc prolongation in the EKG) include amiodarone, dofetilide, pimozide, procainamide, quinidine, sotalol, propafenone, and sparfloxacin among others. QTc prolongation can infrequently result in serious, rarely fatal, irregular heartbeats. Consult your doctor or pharmacist for more details, and for instructions on how you may reduce your risk of this effect.

NOTES: Do not share this medication with others. This medication has been prescribed for your current condition only. Do not use it later for another infection unless told to do so by your doctor. A different medication may be necessary in those cases.

HOW DO I STORE IT?: Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

WHAT IF I MISS A DOSE?: If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: severe or persistent diarrhea.

FOLL

ZITHROMAX # 16.25 ÷ 6 = $ 12.71

$8.325/ea. AZITHROMYCIN

Longs Drugs

27750 SANTA MARGARITA PARKWAY
MISSION VIEJO, CA 92691
PHONE
24 HOUR PHONE(949) 770-9898

05/04/2007 **Rx1442078**
MILLER, BEVERLY
22685 PABLO VENTO

PRATT, DONALD J MD
BX COPAY: $27.48
CASH PRICE: $49.95

AZITHROMYCIN 250 MG TABLET
6 (GREENSTONE LTD.)

RECEIPT

NDC# 59762-3060
EDS 0005
REG# PHY33135
AUTH# 11442078 2007

Your healthcare provider has prescribed azithromycin. Azithromycin is taken once a day for 5 days.

- Take 2 tablets today as your first day's dose. Then take 1 tablet on each of the next 4 days to complete your therapy.
- Azithromycin tablets can be taken with or without food.
- Be sure to finish your medication, because if you quit too soon your infection may return.[1]

The most common side effects of azithromycin are diarrhea (4-5%), nausea (3%), and stomach pain (2-3%). Less than 1% of patients stopped taking this drug due to side effects.

While allergic reactions to this drug are rare, should one occur, stop taking this drug and call your healthcare provider right away.

If you have any questions about this drug or its possible side effects, please talk with your healthcare provider.

azithromycin

tablets

250 mg*

References:
1. Urquhart J. The treatment of bacterial infections. *Patient Outcomes*. March 1994;19-20.

To remove, push tablets through from other side.

Take together

Your first day's dose

Take these 2 tablets as your first day's dose of azithromycin.

Then take 1 tablet each day for the next 4 days.

N 1 03 5976-2306-01-9

Distributed by:
Greenstone Ltd.
Peapack, NJ 07977

71-6331-00-1
820 428 001

d with full prescribing information

IMPORTANT - UNLESS DIRECTED BY PHYSICIAN, ALL MEDICATION MUST BE FINISHED.

DO NOT TAKE WITH ANTACIDS

THIS MEDICINE MAY BE TAKEN WITHOUT FOOD.

IF MEDICATION UPSETS YOUR STOMACH, TAKE WITH A MODEST MEAL, CRACKERS, OR BREAD.

+ equivalent to 250 mg

RECOMMENDED STORAGE: Store between 15° to 30°C (59° to 86°F).
[illegible] accompanying prescribing information.

1 Card x 6 Tablets

Longs Drugs

Store # 0242
3755 SANTA MARGARITA PARKWAY
MISSION VIEJO, CA 92691
24 HOUR PHONE (949) 770-9898
www.longs.com

PRATT, DONALD J MD
Rx 1442078 05/04/2007 BLI
MILLER, BEVERLY
TAKE AS DIRECTED

Generic for ZITHROMAX
AZITHROMYCIN 250 MG TABLET
6 (GREENSTONE LTD.)
NO REFILLS

USE BY 3/09

PINK, OVAL TABLET
Front:G Back:3060

1 Card x 6 Tablets

GREENSTONE® BRAND

azithromycin

tablets

250 mg*

A full course of antibiotic therapy in 5 daily doses

THE HENRY J. KAISER FAMILY FOUNDATION kaisernetwork.org

Kaiser Daily Health Policy Report

Monday, August 06, 2007

Prescription Drugs

Los Angeles Times Series Examines Pharmaceutical Industry Influence on Physicians, Consumers

The *Los Angeles Times* on Monday featured a series of articles titled "Sold on Drugs" that examines the effect of drug manufacturers' marketing techniques on physicians and consumers. Summaries appear below.

- "Under the Influence: Savvy Marketing Whets Our Appetite for Prescription Pharmaceuticals. Consumers, Doctors, Researchers -- No One Is Immune": Drug makers "do everything in their considerable power to ensure that their brand-name prescription medications are on the lips of patients and in the minds of physicians every time the two meet across an exam table," the *Times* reports. The *Times* continues, "A growing chorus of critics says their efforts have begun to rewrite the dialogue between patient and doctor, influence physicians' judgments and open the act of prescribing to forces more profit-minded than sacred" (Healy [1], *Los Angeles Times*, 8/6).

- "From Funding to Findings: When Drug Companies Conduct Research on New Pharmaceuticals, Outcomes May Be Affected -- Greatly": "[M]edical researchers, academic authorities and influential specialists are key players" in the commercial success of a drug, the *Times* reports. Drug manufacturers "build a corps of respected university experts who have lengthy experience with a drug prospect, financial ties to the firm that paid them to study it and, often, a direct stake in its success" when the companies form "commercial partnerships with universities, endow academic programs and teaching chairs, and pay academic medical centers to run clinical trials," according to the *Times* (Healy [2], *Los Angeles Times*, 8/6).

- "Doctor, Just a Little Something for You: Complex Sales Strategies Go Way Beyond Freebies": Drug companies "focus the bulk of their marketing budgets to influence" physician prescribing habits, which "profoundly affect sales of a drug company's products," the *Times* reports. The *Times* notes that drug makers' marketing tactics "reach into physicians' offices, pervade their medical specialty organizations and often shape the messages that doctors receive in educational settings" (Healy [3], *Los Angeles Times*, 8/6).

- "Next Step: Create the Demand; Direct, Emotional Ads for Prescription Drugs Are Everywhere. But They're Just One Way To Get to the Consumer": "With vast and profitable markets up for grabs, drug companies are aggressively reaching beyond doctors and taking their marketing messages directly to consumers," the *Times* reports. FDA in 1997 loosened regulation of direct-to-consumer advertising, a change that "set off explosive growth in marketing aimed at a general audience long on interest and -- compared with physicians -- short on professional skepticism," according to the *Times* (Healy [4], *Los Angeles Times*, 8/6).

- "In Short, Marketing Works: By Targeting Consumers and Doctors -- Directly and Indirectly -- Drug Makers Are Driving Sales. Why Argue With Success?": "The pharmaceutical industry defends its promotional spending as a service to science, physicians and patients," and the ads "also, indisputably, boost sales," the *Times* reports. The *Times* continues, "Physicians see marketing's effects on their patients every day," but "ask the doctors whether the marketing influences their clinical judgments or prescribing behavior, and a chill will descend upon the room," according to researchers who have posed such questions to physicians (Healy [5], *Los Angeles Times*, 8/6).

- "And Now, a Push for Change: Legislators Have Begun To Question the Drug Industry's Pervasive Influence in Health Care. Some Doctors Are Backing Them Up": "In recent years, politicians, consumers and physicians have begun to question sharply the effect of drug makers' commercial appeals," the *Times* reports. "Medical societies and patients groups are quietly debating the wisdom of their dependence on drug companies' largesse," and physicians "are rethinking, or at least disclosing, their ties to drug companies," according to the *Times*. In addition, lawmakers "are drafting and passing bills aimed at blunting the effects of prescription drug marketing," the *Times* reports (Healy [6], *Los Angeles Times*, 8/6).

Los Angeles Times
latimes.com

http://www.latimes.com/features/health/la-he-bribingthegatekeeper6aug06,1,7957877.story?track=rss
From the Los Angeles Times

WOOING THE GATEKEEPER

Doctor, just a little something for you

Complex sales strategies go way beyond freebies.

By Melissa Healy
Los Angeles Times Staff Writer

August 6, 2007

AS guardians of the nation's prescription pads, doctors are the gatekeepers that stand between American patients and the pharmaceutical companies that have drugs to sell them.

Physicians' choices -- whether to medicate, with which medication, generic vs. brand-name drug, and for how long -- profoundly affect sales of a drug company's products. So pharmaceutical manufacturers focus the bulk of their marketing budgets to influence those choices. The drug companies' promotional efforts reach into physicians' offices, pervade their medical specialty organizations and often shape the messages that doctors receive in educational settings.

"There is a big bucket of money sitting in every office" a drug representative visits, said an AstraZeneca marketing director in a widely circulated newsletter interview. "Every time you go in, you reach your hand in the bucket and grab a handful," said Mike Zubillaga, who was fired after his blunt comments made their way onto the Internet last April.

Each day in the United States, an army of roughly 100,000 pharmaceutical company sales reps storms the waiting rooms and offices of the nation's 311,000 office-based physicians. Called "detailers" -- and earning, on average, $81,700 per year -- they are the smiling, well-dressed men and women often seen in a physicians' waiting room toting a cavernous briefcase and making small-talk with the receptionists. Their ranks have more than doubled in the last 10 years.

Sales reps say they want nothing more than to drop off drug samples that doctors can dispense at no cost to their patients, and to brief physicians on the FDA-approved benefits and risks of the prescription drugs their companies make. That's an accurate job description. But it doesn't nearly capture the sophistication of their efforts or the complex web of relationships that marketing departments cultivate with physicians. In recent years, drug-company insiders have come forward to detail the enticements, persuasive techniques and market-tracking systems that their organizations use to nudge doctors' prescribing decisions to boost sales. The picture they provide is of an industry in hot pursuit of physicians' hearts and minds.

Relationships with drug reps

THE inducements that doctors accept are more than just pads, pens and gadgets such as the Viagra calculator that stands up on its base when the "on" button is pushed. A national survey of doctors published in the April 2007 New England Journal of Medicine found that 94% of physicians in the six specialties studied reported some type of relationship with pharmaceutical companies' representatives. Most (83%) received food in their workplace, or accepted drug samples (78%) proffered by visiting representatives. Thirty-five percent reported that drug companies had reimbursed them for the cost of attending professional meetings or company-sponsored sessions that satisfied a physician's "continuing medical education" requirement. And 28% received payments for consulting with a drug company, giving lectures or enrolling patients in trials.

The American Medical Assn. and the pharmaceutical industry group PhRMA adopted non-mandatory codes of conduct in 2002 that discourage the offering or acceptance of items that bring only "personal benefit" to a physician. Shahram Ahari, a former drug rep with Eli Lilly, says that in many cases, those guidelines have given the practice of gift-giving "a nice veneer of respectability."

But the practice's impact is often unaltered -- and may even be greater than when drug reps were permitted to offer extravagant gifts such as theater tickets and golf bags. That is because psychologists have shown consistently that a small token or gesture of friendship often inspires a sharper sense of obligation in the recipient than does a showy gift, for which reciprocation is impossible.

Moreover, Ahari says, "the amount of money invested in gifts hasn't changed. In the past, I could spend $100 on a golf club and give it to you. Now, I can spend $100 on a textbook you need so you can spend your own $100 on that golf club."

Sales reps bear many gifts, but none is more important than the prescription drug samples they bring to doctors. In 2003, the pharmaceutical industry distributed $16.4 million worth of them to doctors, according to PhRMA, the industry's most important trade group.

"For me, that's access," Ahari says. "The doctors are first grateful that you're giving them samples, because it makes them seem like a hero to patients . . . and when they feel that sense of gratitude, they feel obliged to spend some time with the drug rep delivering them." But in the end, it is the patient who often will pay more, because even a short course of sample use builds customer loyalty to a brand-name drug, even when a generic or a cheaper, older drug might be just as effective.

Among the not-so-well-kept secrets of the medical world is the physical attractiveness of the men and women who make up the pharmaceutical sales-rep force. "It seems pretty cynical," says UCLA internist Dr. Martin Shapiro. "I mean, the people that do the detailing aren't your average-looking individuals."

Ahari laughs at the description. Pharmaceuticals' marketing departments look to hire "young, attractive people, quite charismatic" -- and scientific training is completely optional, says Ahari, now a researcher at the UC San Francisco's School of Pharmacy, who describes his former profession on a website (www.Pharmedout.org) devoted to exposing drug company marketing practices.

"They're looking for gender icons -- cheerleaders and ex-military types -- fun to be with, someone with whom you'd like to have a beer or watch a game," Ahari says. To establish friendship and assure access to a physician, a detailer "will scour a doctor's office for objects -- a tennis racquet, Russian novels, '70s rock music," wrote Ahari and Adriane Fugh-Berman, a Georgetown University physician, in an article published by the Public Library of Medicine in April.

Small practices and family physicians are most intensively courted. And doctors whose prescribing practices are not circumscribed by healthcare companies or hospital formularies get extra attention as well. According to the New England Journal of Medicine survey published last April, family practitioners reported they met with pharmaceutical-company detailers, on average, 18 times per month, more than four times the average for all doctors that was reported in a 2000 study. Trailing not far behind them were internists (10 meetings per month), cardiologists (nine) and pediatricians (eight).

Outside the confines of a doctor's office, pharmaceutical marketing efforts become more extravagant.

At physicians' association meetings and at conferences and seminars that provide "continuing medical education" for doctors, drug-company sponsorship is substantial. Both have become important venues for courting physicians over meals and in appealing venues. Both provide opportunities for drug companies, indirectly, to pay speaking fees to favored physicians. And a recent Senate Finance Committee report concluded that, in spite of efforts to stem the practice, both are used by pharmaceutical companies to boost physicians' prescribing of their products.

Sponsorship of seminars

AT a recent hearing of the Senate Committee on Aging, Dr. Jerome Kassirer of Tufts University School of Medicine described meetings of medical societies and associations as "mini-circuses, replete with enormous glittering displays and hovering attractive personnel. Although couched as education," he added, "these marketing efforts are thinly disguised bribes."

UCLA internist Shapiro, who as president of the Society for General Internal Medicine in 2002 sought to limit drug company sponsorship, calls it "the walk of shame." At almost every major medical meeting he attends, he said, "there are these opportunities to get free things that are questionable -- and that clearly are not intended to sharpen the rational decision-making skills of a physician, but to have an impact . . . on how they prescribe medications." It's not enough, he added, to close your eyes and walk past them: Pharmaceutical company money has largely underwritten the programs doctors will attend and the administration of the professional association that organizes the event.

Medical societies "have become dependent on the infamous 'unrestricted grant' from numerous pharmaceutical companies," Dr. J. Gregory Rosenthal, a Toledo, Ohio-based retinal surgeon, told the Senate Committee on Aging in June. "In this context, 'unrestricted' means, 'Use this for whatever you want, but if you ever want another, don't displease us.' "

Physicians' "continuing medical education" requirements also have provided drug companies ripe marketing opportunities, experts say. In 2005, drug companies spent $1.12 billion to fund sessions that physicians attend to maintain their license to practice.

In recent years, new guidelines have sought to distance those grants from companies' marketing departments. Still, the Senate report noted, "drug companies routinely fund educational grants to support programs that favorably discuss the companies' newer and more lucrative products, thereby encouraging physicians to prescribe these products and, ultimately, driving sales." Where doctors are typically a skeptical audience for direct pitches, "when the favorable message is delivered in the context of education -- even if corporate sponsorship is disclosed -- there is an imprimatur ofcredibility and independence," investigators noted.

Some of those programs appear to have been forums for pushing "off-label" uses for prescription drugs, a back-door means of expanding its market. About one-fifth of prescriptions that doctors write are for off-label uses -- to treat a condition other than that for which FDA has found a drug safe and effective. Although it's legal for doctors to write off-label prescriptions, it is illegal for a drug manufacturer to market its drugs for off-label uses.

In 2004, Warner-Lambert (now a division of Pfizer Inc.) paid $430 million to settle claims that it was using continuing education grants to promote off-label uses of Neurontin, an epilepsy drug. In 2005, Serono Laboratories paid $704 million to settle claims in a case that alleged it was using educational programs to boost sales of the AIDS drug Serostim for off-label uses.

The 50 state attorneys general who accepted the settlement of the Neurontin case have used $21 million to establish the Consumer and Prescriber Grant Program, www.ohsu.edu/cpgp/, designed to provide healthcare professionals and consumers information related to prescription drugs and their marketing.

melissa.healy@latimes.com

Los Angeles Times
latimes.com

http://www.latimes.com/features/health/la-he-effectiveness6aug06,1,4029145.story?coll=la-headlines-health
From the Los Angeles Times

THE PAYOFF

In short, marketing works

By targeting consumers and doctors -- directly and indirectly -- drug makers are driving sales. Why argue with success?

By Melissa Healy
Los Angeles Times Staff Writer

August 6, 2007

THE pharmaceutical industry defends its promotional spending as a service to science, physicians and patients. Advertising to patients helps motivate them to improve their health, manufacturers say, and detailing doctors keeps them abreast of new therapies and scientific advances.

Those activities also, indisputably, boost sales. As marketing budgets climbed toward a 2006 high of $28 billion, sales of prescription drugs have never been higher. According to estimates published by the Kaiser Family Foundation, the number of individual prescriptions filled in the United States rose from 2.9 billion in 1999 to 3.7 billion in 2006; in 1994, Kaiser calculated that each American filled on average 7.9 prescriptions per year, including refills; by 2005, that number had risen to 12.4.

For every 10% increase in direct-to-consumer advertisements within a class of similar drugs, sales of drugs in that class (say, antidepressants or erectile dysfunction drugs) went up 1%, Kaiser found in a 2003 study. In 2000, direct-to-consumer advertising alone boosted drug sales 12%, at an additional cost of $2.6 billion to consumers and insurers.

Of more than 10,000 drugs on the U.S. pharmaceutical market, half of all marketing budgets are used to promote 50 brand-name medications, according to a 2003 study in the journal Clinical Therapy. And those 50 drugs are the ones that sell the best.

Prodding patients to prod their physicians, apparently, works. In 2006, a Kaiser Family Foundation survey of 834 office-based physicians found that 28% of doctors said patients "frequently" asked for prescription drugs by name after seeing an advertisement. Although about half said they typically responded by suggesting lifestyle changes, 14% of the physicians said they would, in many cases, prescribe a different drug in the same class as the one the patient requested. And 5% readily acknowledged that they frequently would prescribe the drug the patient requested.

Physicians see marketing's effects on their patients every day. But ask the doctors whether the marketing influences their clinical judgments or prescribing behavior, and a chill will descend upon the room, say those who have run the experiment.

"Physicians are heavily socialized to believe that they have risen above the normal human foibles," said Harvard University's David Blumenthal, co-author of the most recent survey detailing doctor-drug company interactions. "They clearly recognize that physicians are human and subject to normal human influences; they just have a lot of trouble seeing themselves as subject to that."

Not immune to marketing

BLUMENTHAL finds it revealing that most physicians do not extend to their colleagues the same trust. In a widely cited 2001 study published in the American Journal of Medicine, 84% of young physicians surveyed said

they believed that drug industry promotions, including gifts and meals, influenced the prescribing practices of fellow physicians. Although most of these doctors acknowledged they were besieged by back-slapping, sample-toting, gift-giving drug representatives, 61% said they considered themselves immune to marketing's effects.

They are not. A 1994 study found that hospital-based doctors were more likely to request the addition of brand-name prescription drugs to their institution's medicine chest after they had met with sales representatives detailing those drugs.

Studies published in 1988 and 1992 found that physicians who attended continuing medical education programs sponsored by drug companies, or who accepted funding for travel and lodging to attend them, were significantly more likely to prescribe that company's drug than those who did not.

Several studies have found that physicians who accept and hand out free samples to their patients are far more likely to prescribe those drugs than those who don't take or have no access to samples.

Last April, the online medical journal Public Library of Science published a study tracking the effect of doctor-detailing by sales reps working for Warner-Lambert, maker of the anti-epileptic drug Neurontin. The study showed that, following even a brief encounter with a marketing representative detailing Neurontin, almost half of the 97 physicians examined found their briefings highly educational (even when research evidence presented was scant or poor) and indicated they would step up prescriptions of the drug.

Dr. Andrew Leuchter has spent much of the last two years heading a UCLA committee convened to redraft guidelines for physicians' interactions with drug companies. He has faced the skepticism of physicians when the subject of drug company influence is raised.

"They ask, 'Do you really think that my medical decision-making can be influenced by the fact that someone bought me a pizza?' " Leuchter said.

"They're quite sobered" when confronted with the mounting pile of evidence that it can, he added.

Subtly powerful

DR. Kurt Stange, the editor of the Annals of Family Medicine who called for an end to consumer advertising of drugs, said the effects of a detailing visit can be subtle. But, he added, these encounters are made all the more powerful when physicians either deny or ignore their influence.

"You're not overtly thinking, 'I'm going to prescribe this drug because I got a pen," Stange said. "You're just thinking, 'What will help this patient?' and you've been bombarded with advertisements, and the name is always before you. . . . You have to have a fair amount of self-awareness to notice that."

In the end, advocates of reform say, there is no stronger evidence that drug marketing influences behavior than the simple fact that drug companies do market their products -- and that they are spending more money doing it than ever before. The makers of the nation's bestselling drugs field on average 4,000 sales representatives to detail doctors, staff booths at medical meetings and organize trips and meals for doctors, and spend more than $1 billion per year to market drugs to physicians alone. They spend, all told, roughly $5 billion a year to advertise directly to consumers. Though they are not counted in marketing budgets, the funds they dispense to support research, medical professional organizations and patient-advocacy groups run into the billions.

In terms of cold, hard return-on-investment, that money was well spent, says a study unveiled in 2001. Tracking prescription sales for 391 drugs and company marketing budgets from 1995 through 1999, Dartmouth College marketing professor Scott Neslin has calculated, down to the penny, how well increases in marketing pay off.

Each additional dollar spent on advertising in medical journals brought $5 worth of sales of a drug, Neslin found, and an extra dollar devoted to sponsorship of continuing medical education and professional meetings yielded an average of $3.56 in sales. A dollar spent on physician-detailing generated sales, on average, was worth $1.72. But

in the case of the most aggressively marketed drugs, that dollar generated sales of more than $10.

Appealing directly to consumers was lucrative, Neslin found, but a little less than wooing physicians. Each dollar spent on direct-to-consumer advertising generated, on average, increased sales of $1.37.

Such calculations flesh out a self-evident truth, said, UCLA's Dr. Martin Shapiro, a past president of the Society of General Internal Medicine and an advocate of reform in the relationship: "These are large and sophisticated organizations. . . . They would not be spending that money if it didn't work."

melissa.healy@latimes.com

Los Angeles Times
latimes.com

http://www.latimes.com/features/health/la-he-reforms6aug06,1,2797596.story?coll=la-headlines-health
From the Los Angeles Times

SOLD ON DRUGS

And now, a push for change

Legislators have begun to question the drug industry's pervasive influence in healthcare. Some doctors are backing them up.

By Melisa Healy
Los Angeles Times Staff Writer

August 6, 2007

FOR Dr. Howard Brody, nearly three decades of family medical practice has afforded a clear view of the rising tide and spreading effects of drug industry marketing. As Brody entered the profession in 1977, that tide was coming in gradually. In the last decade, it has surged to account for at least $30 billion a year in spending.

Now 58, Brody sees a shift in the marketing tide. In recent years, politicians, consumers and physicians have begun to question sharply the effect of drug makers' commercial appeals. Medical societies and patients groups are quietly debating the wisdom of their dependence on drug companies' largesse. Doctors are rethinking, or at least disclosing, their ties to drug companies. Legislators are drafting and passing bills aimed at blunting the effects of prescription-drug marketing.

Along the way, Brody has evolved from family physician to medical ethicist. Now a professor of family medicine and director of the University of Texas' Institute for the Medical Humanities, Brody has been among those who have fomented a backlash.

For several years in his earliest days as a family physician in Michigan, Brody received a long line of drug representatives bearing gifts, jokes, an occasional journal article and, most important, drug samples. The exchanges troubled him in ways that, as a young doctor in the late 1970s, he found difficult to put his finger on. But when he joined the medical faculty at Michigan State University and had the choice of opting out of such meetings, he did so with relief.

Two decades later, Brody read a commentary in the Journal of the American Medical Assn. that stirred up the same disquiet he remembered from his days meeting with drug reps. The 1997 JAMA editorial, "Thyroid Storm," told readers of a disputed study comparing thyroid medications. The study was conducted at UC San Francisco and was sponsored by Boots Pharmaceuticals Inc., a firm with strong commercial interests at stake. The study's findings came to a conclusion contrary to the sponsor's interests, and Boots threatened legal action if the study was published.

"The research community is getting progressively more entangled with industry, as became evident to me when I tried to find thyroid experts to review the paper who did not have financial ties" to Boots, wrote then-JAMA editor Dr. Drummond Rennie. The American Thyroid Assn. failed to rally to the researcher's aid, leaving "the sad impression that the ability of the association to influence these events was weakened by its heavy dependence" on the drug maker's financial support, Rennie wrote.

Brody found Rennie's account of the episode deeply shocking. But this time, his uneasiness found its voice. Starting in 2001, Brody began suggesting, at professional meetings and in conversations with fellow physicians, that the marketing of pharmaceuticals to doctors -- indeed the pervasive influence of drug makers within the medical profession -- had gone too far.

His colleagues' response was "very negative, very hostile," he recalls. "It really sounded like, 'Who are you, sounding so scolding? You think you're better than us. How dare you?' There had been this gradually creeping seduction going on all these years . . . and the pharmaceutical industry had happily supplied us with justifications for it. We doctors lapped them up eagerly."

But by 2004, those days were ending. The Annals of Family Medicine published an essay by Brody, "The Company We Keep: Why Physicians Should Refuse to See Pharmaceutical Representatives." (Brody went on to write a book, "Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry," published this year.) Former New England Journal of Medicine editor Dr. Marcia Angell published "The Truth About the Drug Companies: How They Deceive Us and What to Do About It." Her fellow NEJM editor, Dr. Jerome Kassirer, continued with "On the Take: How Medicine's Complicity With Big Business Can Endanger Your Health."

At a 2004 meeting of the American College of Rheumatology, physicians reeling from public outcry over the market withdrawal of the arthritis drugs Vioxx and Bextra vowed to wean their organization from its heavy dependence on pharmaceutical funding, setting off similar self-examination among other medical societies. While acknowledging that pharmaceutical sponsorship accounted for 34% of the group's income, its president at the time, Dr. David Wofsy, declared that the group's leaders, its young physicians, its political principles and its silence were "not for sale."

In statehouses across the country, lawmakers began to hammer out laws aimed at blunting the reach and effect of drug makers' marketing efforts.

To date, at least 30 states have enacted laws, or have considered legislation, that would do so. Those include bills requiring the disclosure of gifts and payments by drug makers to physicians, limits on pharmaceutical companies' access to prescription information used for marketing purposes, advertising restrictions and limits on pharmaceutical sales representatives' gift-giving to doctors. California and Virginia have joined Vermont, Maine and Minnesota -- three states that have enacted the most sweeping laws on drug marketing -- in requiring reports disclosing drug makers' spending on advertising and marketing activities.

On Capitol Hill, a handful of lawmakers have launched hearings on the subject and suggest that legislation could come next. After presiding over a June 27 Senate hearing titled "Paid to Prescribe?," Sen. Herb Kohl (D-Wis.) suggested he would ask the prestigious Institute of Medicine to weigh in on the subject. He warned drug industry representatives to expect "progress" from a newly Democratic Congress.

The bid to curb drug industry marketing is hardly a juggernaut. Many of the state initiatives have been challenged as infringements on free-speech rights. Some have met resistance from physicians. Virtually all have been opposed by the drug industry, which, according to estimates by the Center for Public Integrity, has spent $758 million on lobbying -- more than any other industry -- since 1998.

Among rank-and-file doctors, Brody sees "almost a sea change" in attitudes toward drug marketing. For veteran physicians, the hostile defensiveness is no longer a reflex, he said. Among younger doctors and medical students, he sees genuine interest in reducing the influence of drug company marketing on the front lines of medicine.

Medical schools such as Stanford, University of Pennsylvania, Yale and, most recently, UC Davis and UCLA have sought to tighten rules governing relationships between physicians and drug makers, including a prohibition on the acceptance of even small gifts from drug reps.

Many medical students also have organized to resist the commercial entreaties of drug makers. Since 2002, the American Medical Students Assn. has banned pharmaceutical advertising and sponsorships of national and regional meetings, as well as advertising on its website or in its magazine. The group's "PharmFree" campaign urges medical students to shun seminars and lunches sponsored by drug companies.

The sea change Brody perceives appears to have come too late to head off the swelling wave of state initiatives and public calls for reform. Although doctors understandably resist the efforts of politicians to regulate the

practice of medicine, Brody said they should have seen this coming. "The more we're seen as feeding on the largesse of the pharmaceutical industry, the less grounds the public has to have confidence in our putting their interests first, and the more they're going to try to step in and mandate reforms," Brody said. "I have to say, 'Gosh darnit, what did you expect, guys?' "

Los Angeles Times
latimes.com

http://www.latimes.com/features/health/la-he-drugintro6aug06,1,6647049.story?track=rss
From the Los Angeles Times

SOLD ON DRUGS

Under the influence

Savvy marketing whets our appetite for prescription pharmaceuticals. Consumers, doctors, researchers -- no one is immune

By Melissa Healy
Los Angeles Times Staff Writer

August 6, 2007

FOR many Americans, a doctor's decision to prescribe medication is something of a sacred transaction. A physician considers the patient and symptoms and chooses the best drug for the job, drawing upon years of training and clinical experience. It is an exchange conducted in a hushed sanctuary, far from the heat and noise of the marketplace -- a place where cool judgment reigns.

That sanctuary has been breached. Today, drug manufacturers do everything in their considerable power to ensure that their brand-name prescription medications are on the lips of patients and in the minds of physicians every time the two meet across an exam table. A growing chorus of critics says their efforts have begun to rewrite the dialogue between patient and doctor, influence physicians' judgments and open the act of prescribing to forces more profit-minded than sacred.

In 2006, drug-makers spent almost $5 billion to reach out to consumers with direct advertising. But the glossy magazine ads and buzz-generating TV spots are just the most visible parts of a campaign to build and nourish markets for brand-name prescription products. The world's pharmaceutical companies spend an estimated $19 billion annually to woo doctors. They sponsor teaching programs and research at universities across the country, gaining goodwill along the way. They give money to patient groups. They hire public relations firms to share patient stories of illness and triumph.

In a nation that consumed $279-billion worth of prescription medications in 2006 -- spending 80% of that on brand-name products -- their efforts appear to be paying off. Americans filling a prescription choose brand-name products 37% of the time, even though three-quarters of all prescription drugs in the U.S. are available in cheaper generics.

"The most effective marketing is the marketing you're not aware of," says Dr. Peter Rost, a one-time pharmaceutical company marketing executive who has become an Internet-based industry watchdog. "If you see an ad, you know it's marketing. But if a friend or your doctor talks to you about a drug, you don't."

Now the size, scope and apparent effectiveness of drug companies' marketing efforts has begun to prompt cries of foul even from within the medical establishment, which has long been silent about its growth. In a handful of state legislatures across the country, lawmakers already have acted to blunt drug-company marketing, and many more are considering similar measures. Lawmakers on Capitol Hill have suggested that federal legislation may come next.

At stake, critics say, are patients' health, the nation's healthcare budget and, ultimately, the trust and esteem in which Americans hold their physicians. Costs rise as more doctors prescribe brand-name drugs when cheaper, older or more effective drugs might be available.

Under-treated conditions that threaten the lives and wellness of large swaths of the population -- illnesses such as

diabetes and high blood pressure -- may get less attention than conditions such as erectile dysfunction or insomnia, for which pharmaceutical firms have new and potentially more profitable offerings. And patients may be steered toward newer drugs with risks and side effects that are less well-known, in lieu of medications with a longer history of safe use.

"There is nothing fundamentally wrong with advertising products," Dr. Jerome P. Kassirer, a former editor of the New England Journal of Medicine, told a Senate committee recently. "But when financial incentives yield inappropriate or dangerous care, when they inordinately raise the cost of care, when they risk patients' lives in clinical trials, and when they damage the profession, they have gone too far."

The pharmaceutical industry counters by arguing that its marketing efforts are needed to recoup the cost of drug development and that they introduce Americans to medicines that can save lives and improve well-being. The industry's sponsorship of research and education pushes the process of drug discovery and development forward, drug-makers say. Companies' marketing to physicians keeps busy clinicians abreast of new therapies and scientific advances in a fast-changing landscape. And their advertising of drugs in mass-media outlets educates patients and improves their communication with doctors, they add.

And drug marketing improves the economic vitality of the nation, a representative of the drug industry's largest trade group, PhRMA, said at a recent Senate hearing. Prompted by drug industry marketing, more patients in recent years have sought out a doctor, and more doctors have looked for signs of under-treated conditions such as depression, diabetes and asthma among patients, Marjorie E. Powell, an attorney for PhRMA, said to the Senate Select Committee on Aging in late June. Citing a pair of studies published in 2003, Powell said that in the long run, increasing treatment of such chronic conditions should drive down the nation's healthcare bill.

As the debate rages -- among doctors, within universities, in statehouses across the nation and in the halls of Congress -- here is a look at a wide range of marketing efforts that has touched it off.

Los Angeles Times
latimes.com

http://www.latimes.com/features/health/la-he-buildingthemarket6aug06,1,124572.story?coll=la-headlines-health&ctrack=3&cset=true
From the Los Angeles Times

BUILDING THE MARKET

From funding to findings

When drug companies conduct research on new pharmaceuticals, outcomes may be affected -- greatly

By Melissa Healy
Los Angeles Times Staff Writer

August 6, 2007

FROM the time that a drug is little more than a promising compound until well into its commercial life span, medical researchers, academic authorities and influential specialists are key players in its commercial viability.

Drug companies regularly enter into commercial partnerships with universities, endow academic programs and teaching chairs, and pay academic medical centers to run clinical trials. In doing so, they build a corps of respected university experts who have lengthy experience with a drug prospect, financial ties to the firm that paid them to study it and, often, a direct stake in its success. These university-based physicians enjoy a public perception of scholarly impartiality as well, which can make them influential voices when they speak in favor of a medication or treatment.

In 2 1/2 decades, drug companies' funding of biomedical research -- much of it conducted at universities -- has risen from $1.5 billion to $55 billion. In the United States, pharmaceutical investment in biomedical research has outpaced and, ultimately, overtaken the federal government's investment in such research, expected this year to be about $36 billion. The university-based researchers and physicians who conduct this work often serve on or testify before committees that advise the Food and Drug Administration on drug approvals. They then play a vital role in building markets for new and existing prescription medications -- this time by serving on expert committees that write treatment guidelines and standards. These "clinical practice guidelines" enshrine the medical profession's consensus about which patients should be treated for certain conditions, and how. Drug company marketing departments prize these recognized authorities as "opinion leaders" and cultivate them accordingly.

A New England Journal of Medicine article in April surveying relationships between physicians and pharmaceutical companies found, for instance, that developers of clinical guidelines were 41% more likely to have received payments from drug companies for consulting, lecturing or trial recruitment than physicians not involved in guideline development. Physicians teaching at medical schools were 67% more likely to have received such payments than those who did not teach.

The power that clinical guidelines hold to expand the market for a drug is immense.

In May 2003, for instance, a government-sanctioned panel of experts revised the definition of which patients should receive prescription medication to control high blood pressure. Overnight, the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure expanded the market for blood pressure drugs by millions of new patients. Nine of the 11 authors of the report had financial ties to companies likely to benefit from the new guidelines. Six had conducted research under grants provided by one or more of the four pharmaceutical giants that held patents on prescription drugs used to treat high blood pressure.

Wider market for statins

IN July 2004, the National Cholesterol Education Program conducted a similar revision of the clinical guidelines

for diagnosing and treating high cholesterol in adults. With the new guidelines' publication, 8 million Americans became candidates for cholesterol-lowering drugs -- three years after an earlier guideline had added 23 million to the potential rolls. Most of the committee members were subsequently found to have had extensive ties to companies that make statins, widely used in the treatment of high cholesterol.

Guidelines like these are clearly saving many lives. But they also have made Americans with elevated blood pressure the most aggressively medicated patients in the world. A January study in the Archives of Internal Medicine found that 64% of patients diagnosed with hypertension in the United States were getting two classes of drugs to treat the condition -- compared with 59% of British and German patients with high blood pressure and 49% in Spain.

The guidelines also have made statins -- led by Pfizer's Lipitor -- the world's bestselling prescription medications, despite growing questions about their appropriateness for many users. The 1994 edition of the psychiatry profession's single most influential guideline, the Diagnostic and Statistical Manual of Mental Disorders, was recently found to have been written by a panel of experts among whom 56% had at least one financial relationship with a pharmaceutical manufacturer. For experts writing guidelines for severe mental illness such as bipolar disorder and schizophrenia -- diagnoses that have been broadened significantly in recent years -- 100% had ties to drugmakers, according to the study, which was published in Psychotherapy and Psychosomatics.

"At present, the financial ties between the guidelines panels and industry are extensive," wrote Dr. Robert Steinbrook in the Jan. 25 issue of the NEJM.

THE HENRY J. KAISER FAMILY FOUNDATION kaisernetwork.org

Richie Ed

Kaiser Daily Health Policy Report

Wednesday, August 08, 2007

Prescription Drugs

Use of Generic Prescription Drugs Increasing as Patents Expire on Blockbuster Medications; Trend Expected To Reduce Overall Drug Spending

As patents expire over the next five years for brand-name prescription drugs with more than $60 billion in combined annual sales, some health care experts predict that new generic equivalents will maintain single-digit drug price inflation for U.S. consumers, the *New York Times* reports. Generic drugs typically are 30% to 80% less expensive than brand-name versions, contain the same active ingredients and are approved by FDA under the same standards as brand-name drugs.

Expiring patent protection for some drugs, such as Sanofi-Aventis' sleeping pill Ambien, has been cutting into brand-name manufacturers' revenue, and several blockbuster drugs are set to face generic competition over the next five years, including Fosamax, a drug that slows bone loss, and the cholesterol-lowering drug Lipitor, the *Times* reports. Some companies, such as pharmacy benefit manager Express Scripts, and Medicare prescription drug plans are encouraging use of generics by lowering copayments for the drugs versus their brand-name equivalent.

Ronny Gal, an analyst for Sanford C. Bernstein, says that by 2010, profits for generic drug manufacturers are expected to grow by 10% to 13% annually. The generic movement is "good for everybody but the branded pharmaceutical companies," Gal says.

Brand-name drug makers are addressing the loss of patent protection by developing new drugs, creating generic subsidiaries and contracting for the production of company-authorized generics. The Pharmaceutical Research and Manufacturers of America says that despite declining profits, the drug makers are increasing research and development budgets each year. However, the *Times* reports that "there are fewer potential blockbuster drugs" in manufacturers' pipelines that could take the place of drugs that go off patent.

Richard Evans -- a consultant with Avos Life Sciences, which does research and consulting for the pharmaceutical industry -- said, "At the end of the day, it's basically a failure of innovation." Caroline Loew, PhRMA's senior vice president of scientific and regulatory affairs, said, "I don't think we would support the contention that there's a lull," adding that the industry is trying to develop treatments for more complex conditions that take longer to research. However, brand-name drug makers face challenges. "There's a tidal wave of generic drugs, and we are just in the beginning of the tidal wave," Laizer Kornwasser, an executive for drug plan provider Medco Health Solutions, said (Saul, *New York Times*, 8/8).

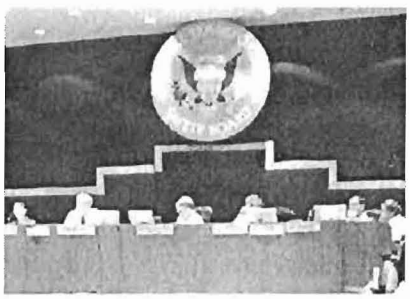
DRUG TOPICS
150 Years of Dedication to Pharmacy

Med Guides

FDA hears of problems with Med Guides

FDA hears of problems with Med Guides

Jul 9, 2007
By: Kathryn Foxhall
Drug Topics



FDA addresses concerns over Medication Guides

The Food & Drug Administration's Medication Guide program, set up nine years ago as a way to inform patients about the risks or special issues with certain drugs, has a host of problems, according to pharmacists and other witnesses at a recent hearing. For specific drugs with serious public health concerns, the agency requires pharmacists to distribute—with each prescription and refill—written patient information that is approved by FDA and provided by the manufacturer.

A public hearing, aimed at improving the guides, was held last month in Washington, D.C. At the hearing, the FDA heard that manufacturers often don't ship the guides, that pharmacists often don't distribute them, and that patients often find them difficult to understand and end up throwing them away.

Originally conceived as a requirement for only a few drugs, Med Guides are now required for 240 products, according to FDA.

A big issue, said Gerald McEvoy, assistant VP of ASHP, "is the consumer confusion that exists with the array of documents provided." He pointed out that consumers also get the "Consumer Medication Information" (CMI), the "Patient Package Inserts," and the latest risk communication document, called "Patient Information Sheets."

"One of our principal concerns is the lack of research concerning the role, scope, and effects of the medication guide program on patient understanding and behavior," McEvoy said. "And one of our principal recommendations would be that we need to do research to define what will work best and what is in the best interest of patients."

Marcie Bough, Pharm.D., federal regulatory affairs director with the American Pharmacists Association, told the FDA, "Unfortunately, the Med Guide program is becoming a burden on the pharmacists' time, workflow, and ability to provide patient care." She said APhA asked 396 pharmacists about the Med Guides and found that less than 10% of the providers said the program was working at least moderately well. "The majority of the respondents said that Med Guide information overlaps with other information that patients are receiving, such as CMI, that there is too much information in the Med Guide for some patients to understand, and that it is not written at a consumer-friendly, health literacy level."

Bough went on to say that pharmacists complain they do not get enough copies of Med Guides for distribution, and because the documents have different sizes and formats, there are constant problems in storing, organizing, and finding them.

Several speakers indicated that the time has come to allow electronic distribution of the guides, but there were different ideas on how that might be done. Pharmacy organizations indicated concern that electronic distribution would shift the cost of printing to pharmacists. Speakers noted that the guides were each originally conceived as perhaps two pages long but that now many are several times that length. A number of witnesses urged that such risk communication be done by physicians or that the guides be given to the patient at the point of prescribing.

Paul Seligman, M.D., MPH, associate director of Safety Policy and Communication in FDA's Center for Drug

Evaluation and Research, asked whether physicians are ready to accept that burden on their time.

Jeffrey Stoddard, M.D., VP of Covance, a research and testing company, said, "My sense is that increasingly physicians are acknowledging that risk communication is a critical part of what they have to do and that often it does involve formal mechanisms, including documentation."

Bough said APhA "strongly encourages the agency to include in its review of the Med Guide program the prospect of expanding access to the pharmacist-provided medication therapy management or MTM services for patients on medications that require a Med Guide."

A transcript and other information about the meeting are due to be posted on the FDA Web site. Comments on Med Guides will be accepted through July 12 at: **http://** www.fda.gov, under "Reference Room," then under "Dockets."

THE AUTHOR is a writer based in the Washington, D.C., area.

Public Ed

July 17, 2007

Business

'Marketplace' Report: Drug Guarantees

Day to Day, July 17, 2007 · What if medicine came with a money-back guarantee? Drug manufacturer Johnson & Johnson has proposed paying back insurers if their cancer drug, Velcade, doesn't shrink a patient's tumor sufficiently. Other drug companies are now considering similar types of drug guarantees.

Steve Tripoli of *Marketplace* talks with Deborah Amos about this new pay-for-performance drug pricing.

Public Ed

July 14, 2007

Pricing Pills by the Results

By ANDREW POLLACK

Drug companies like to say that their most expensive products are fully worth their breathtaking prices. Now one company is putting its money where its mouth is — by offering a money-back guarantee.

Johnson & Johnson has proposed that Britain's national health service pay for the cancer drug Velcade, but only for people who benefit from the medicine, which can cost $48,000 a patient. The company would refund any money spent on patients whose tumors do not shrink sufficiently after a trial treatment.

The groundbreaking proposal, along with less radical pricing experiments in this country and overseas, may signal the pharmaceutical industry's willingness to edge toward a new pay-for-performance paradigm — in which a drug's price would be based on how well it worked, and might be adjusted up or down as new evidence came in.

"I think payers will say, 'If the product works and it creates value, we will reward you for it,' " said Anthony Farino, a pharmaceutical industry consultant at PricewaterhouseCoopers. " 'If not, we won't reward you.' "

It is far too soon to tell whether such a pricing paradigm can actually work, in particular because it can be difficult in many cases to measure how well a drug is working. And the approach would probably be most feasible in countries, like Britain, where the government is the primary payer.

But even here in the United States, Medicare and private insurers are already experimenting with new ways to create cost-justified payment systems for medical treatments.

The potential benefits might go beyond simply saving money. Pay-for-performance pricing could make it easier for patients and their doctors to try expensive treatments without busting the bank or forcing insurers to make all-or-nothing decisions about reimbursement.

That was the rationale behind another experiment that is already under way in Britain. Four makers of multiple sclerosis drugs have agreed eventually to lower the prices of their drugs — which can currently cost as much as $18,000 a year — if the medicines do not fully meet expectations.

GlaxoSmithKline also says it has made similar agreements with two European governments, although it declined to identify either the countries or the drugs involved.

Such "risk sharing" deals, as they are being called, would be harder to arrange in this country. "There's no

way we could ask for it and have any leverage," said Dr. Lee N. Newcomer, senior vice president for oncology at the large American insurance company UnitedHealthcare. He said that state regulations and marketplace pressures make it virtually impossible for an insurer to refuse to pay for a drug that has been approved by the Food and Drug Administration, regardless of its price.

Yet UnitedHealthcare is trying a risk-sharing experiment with Genomic Health, a company that sells a $3,460 genetic test meant to help determine whether a woman with early-stage breast cancer would benefit from chemotherapy.

The insurer has agreed to pay for the test for 18 months while it and Genomic Health monitor the results. If too many women are still receiving chemotherapy even if the test suggests they do not need it, Dr. Newcomer said, UnitedHealthcare will seek to negotiate a lower price on the ground that the test is not having the intended impact on actual medical practice.

"The point is to try to make the manufacturer responsible for how their product is used in the medical marketplace," he said.

Genomic Health said it could not comment on individual contracts but acknowledged it was working with various payers on performance-based contracts.

The pharmacy benefit management arm of Cigna, another big American insurer, has a more audacious idea. It is trying to persuade the makers of cholesterol-lowering pills to agree to pay the medical expenses of patients who suffer heart attacks even though they have been steadfastly taking their medicine.

"It's their opportunity to show they stand behind their medication and are confident of the results," said Thom Stambaugh, the chief clinical officer for Cigna Pharmacy Management. He said that the drug companies seemed interested in at least considering the proposition.

Pfizer, which makes the best-selling cholesterol pill Lipitor, said it did not comment on confidential discussions with individual managed care organizations, though it was always receiving proposals.

Medicare, meanwhile, has agreed to pay for certain expensive products or procedures — like some implantable heart defibrillators and the use of PET scans to detect dementia — only if the patients participate in studies to assess the long-term benefits.

Medicare could eventually use such data to decide whether to pay for the product or procedure. However, it does not have the authority to negotiate prices, said Dr. Sean Tunis, a former chief medical officer of Medicare and a major architect of the evidence-gathering policy.

Some companies that sell expensive drugs — including Genentech, which makes cancer treatments, and Genzyme, which makes drugs for rare diseases — said they were not involved in or considering any risk-sharing plans. They said they already helped make their drugs available to patients who cannot afford them.

Genentech also said it was working on tests to better determine which patients should get a drug in the first place.

But drug companies might need to be more flexible in countries like Britain, where drugs are paid for only if they are deemed cost-effective — as measured by how much the health system must pay to achieve certain gains in the length and quality of patients' lives.

"If we didn't enter into the risk-sharing scheme, we wouldn't really have a market here in the U.K," said Pete Smith, a manager in Britain for Biogen Idec. The company makes Avonex, a multiple sclerosis drug that costs the equivalent of about $18,000 a year in Britain and is covered under the risk-sharing arrangement.

Under the plan, about 5,000 M.S. patients are being followed for 10 years to see how well the drugs do in slowing the progression of the disease. The prices of the drugs will be adjusted along the way, so that they remain within a certain limit in terms of cost-effectiveness.

But measuring improvements in the quality of life is an imprecise science at best. The scale used to measure the disease's severity, for example, focuses too much on a patient's mobility and not enough on other problems associated with multiple sclerosis, like fatigue and mental decline, said Nicola Russell, director of services for the MS Trust, a philanthropy that administers the program. "We're stuck with it because nobody's come up with anything better," she said.

Moreover, the plan has been slow to start rolling. It started in 2002, but the first data analysis is only now about to take place.

Johnson & Johnson's money-back proposal on Velcade, known generically as bortezomib, was also made under some duress. An advisory body that decides which drugs the health service pays for in Britain, initially ruled against Velcade. The group said that although the drug had been approved to treat relapses of multiple myeloma, a cancer of the bone marrow, it was not cost effective.

Cancer patients protested, led by the Velcade Three — three Yorkshire women with multiple myeloma who confronted the nation's health secretary and said they were being condemned to die. After patient groups and the company won an appeal forcing the matter to be reconsidered, Johnson & Johnson made its money-back offer as a way get the drug designated as cost-effective.

"At the end of the day all pharmaceutical companies want to ensure that all patients have access to their therapies," said Kate Purcell, a spokeswoman for Johnson & Johnson.

Under the proposal, which the company's Janssen-Cilag unit and the government hope to complete in the next few weeks, all patients would be eligible for four cycles of treatment, which costs about $24,000.

If the tumors appear to have shrunk by that point, as determined by a blood test, treatment would continue, usually for another four cycles, and the health service would pay. If tumors have not shrunk, treatment

would stop and the company would pay back the money spent on the drug up to that point.

But Janssen-Cilag and the government advisory committee disagree on how much the tumors must shrink for treatment to continue.

The government is proposing at least a 50 percent reduction, known as a partial response, in a telltale protein produced by the tumors. The company is arguing that a 25 percent reduction, known as a minimal or minor response, should be enough. The company and some other experts argue that some patients who have only a minimal response after four cycles later go on to have complete remissions with further treatment.

"It just seems to me wrong to a patient if you've received a minor response rather than a partial response that you can't go on and receive treatment," said Dr. Paul S. Richardson, a researcher at the Dana-Farber Cancer Institute in Boston. He has led several Velcade clinical trials and has received speaking fees from Johnson & Johnson, which distributes the drug overseas, and from Millennium Pharmaceuticals, which developed the drug and sells it in the United States.

If the kinks are hard to work out in Britain, pay-for-performance pricing may be even harder to introduce in the United States, where patients help pay for their drugs.

Dr. Tunis, the former Medicare chief medical officer, said an American biotechnology company sought his opinion about whether to offer a money-back plan on a new cancer drug.

"I and others suggested a money-back guarantee on a cancer drug looked silly," said Dr. Tunis, who is now director of the nonprofit Center for Medical Technology Policy. " 'Oh, I'm sorry your grandma died. Here's your money back.' "

Public Ed

sacbee.com
The Web Site of The Sacramento Bee

This story is taken from Health & Science News at sacbee.com.

AMA wants probe of store clinics

By LINDSEY TANNER -- AP Medical Writer
Published 2:49 pm PDT Monday, June 25, 2007

CHICAGO (AP) The American Medical Association wants authorities to investigate whether quickie retail-based health clinics run by pharmacy chains pose conflicts of interest that put profits ahead of patient health.

The nation's largest physicians' group on Monday adopted a resolution vowing to seek an investigation after several AMA doctors complained that the clinics interfere with the traditional practice of medicine.

The AMA wants state and federal agencies to look into whether pharmacy chain-owned clinics located in the stores urge patients to get their prescriptions filled on site, which the AMA maintains would pose a conflict. It also said that insurance companies should be banned from waiving or lowering co-payments only for patients who get treatment at store-based clinics.

A spokesman for Deerfield, Ill.-based Walgreen Co., which operates 63 clinics in its stores in six states, said customers aren't steered to Walgreen pharmacies, and are allowed to get prescriptions filled wherever they choose.

He said the AMA action was misguided and that any investigation would find no problems.

"If the AMA pushes this agenda, its members may find out that legislators and constituents have been demanding accessible, affordable and high-quality health care for years and that's what retail clinics are delivering," Walgreen spokesman Michael Polzin said.

Walgreen is expanding its clinics and expects to have 400 by the end of 2008, he said.

The measures adopted at the group's annual policy meeting rejected some physicians' requests that the AMA oppose the clinics outright.

"If we believe in consumer-driven medicine, if we believe that it is the responsibility of medicine to respond to the needs of our patients and if there is a strong consumer demand, then we in fact are going to have to compete in this arena," said Dr. Peter Carmel, an AMA board member.

There are about 500 retail-based health clinics nationwide, said Michael Howe, chief executive officer of MinuteClinic, a Minneapolis-based chain of about 200 clinics in 20 states. It was acquired by CVS Corp. last year.

The clinics typically offer same-day appointments plus weekend and evening hours for routine health problems, including sore throats and ear infections. Generally staffed by nurse-practitioners or physician assistants, the clinics often charge less than traditional doctors' visits.

Howe said the clinics are intended to supplement, not replace, traditional doctor-patient relationships, and that opposition comes from "the fringe in the medical community."

Kirsten Harrison, 39, a Minneapolis-area office manager, said she uses the clinics frequently when her children's doctor is booked up.

"If it's strep throat, I can't wait two days to get them into the physicians' office," Harrison said. "It's just been so efficient."

Go to: Sacbee / Back to story

Public Ed

July 3, 2007

Keeping Patients' Details Private, Even From Kin

By JANE GROSS

An emergency room nurse in Palos Heights, Ill., told Gerard Nussbaum he could not stay with his father-in-law while the elderly man was being treated after a stroke. Another nurse threatened Mr. Nussbaum with arrest for scanning his relative's medical chart to prove to her that she was about to administer a dangerous second round of sedatives.

The nurses who threatened him with eviction and arrest both made the same claim, Mr. Nussbaum said: that access to his father-in-law and his medical information were prohibited under the Health Insurance Portability and Accountability Act, or Hipaa, as the federal law is known.

Mr. Nussbaum, a health care and Hipaa consultant, knew better and stood his ground. Nothing in the law prevented his involvement. But the confrontation drove home the way Hipaa is misunderstood by medical professionals, as well as the frustration — and even peril — that comes in its wake.

Government studies released in the last few months show the frustration is widespread, an unintended consequence of the 1996 law.

Hipaa was designed to allow Americans to take their health insurance coverage with them when they changed jobs, with provisions to keep medical information confidential. But new studies have found that some health care providers apply Hipaa regulations overzealously, leaving family members, caretakers, public health and law enforcement authorities stymied in their efforts to get information.

Experts say many providers do not understand the law, have not trained their staff members to apply it judiciously, or are fearful of the threat of fines and jail terms — although no penalty has been levied in four years.

Some reports blame the language of the law itself, which says health care providers may share information with others unless the patient objects, but does not require them to do so. Thus, disclosures are voluntary and health care providers are left with broad discretion.

The unnecessary secrecy is a "significant problem," said Mark Rothstein, chairman of a privacy subcommittee that advises the Department of Health and Human Services, which administers Hipaa. "It's drummed into them that there are rules they have to follow without any perspective," he said about health care providers. "So, surprise, surprise, they approach it in a defensive, somewhat arbitrary and unreasonable way."

Susan McAndrew, deputy director of health information privacy at the Department of Health and Human Services, said that problems were less frequent than they once had been but that health care providers continued to hide behind the law. "Either innocently or purposefully, entities often use this as an excuse," she said. "They say 'Hipaa made me do it' when, in fact, they chose for other reasons not to make the permitted disclosures."

Mr. Rothstein, one of Hipaa's harshest critics, has led years of hearings across the country. Transcripts of those hearings, and accounts from hospital administrators, patient advocates, lawyers, family members, and law enforcement officials offer an anthology of Hipaa misinterpretations, some alarming, some annoying:

¶Birthday parties in nursing homes in New York and Arizona have been canceled for fear that revealing a resident's date of birth could be a violation.

¶Patients were assigned code names in doctor's waiting rooms — say, "Zebra" for a child in Newton, Mass., or "Elvis" for an adult in Kansas City, Mo. — so they could be summoned without identification.

¶Nurses in an emergency room at St. Elizabeth Health Center in Youngstown, Ohio, refused to telephone parents of ailing students themselves, insisting a friend do it, for fear of passing out confidential information, the hospital's patient advocate said.

¶State health departments throughout the country have been slowed in their efforts to create immunization registries for children, according to Dr. James J. Gibson, the director of disease control in South Carolina, because information from doctors no longer flows freely.

Teaching staff to protect records is easier than teaching them to share them, said Robert N. Swidler, general counsel for Northeast Health, a nonprofit network in Troy, N.Y., that includes several hospitals.

"Over time, the staff has become a little more flexible and humane," Mr. Swidler said. "But nurses aren't lawyers. This is a hyper-technical law and it tells them they may disclose but doesn't say they have to."

Many experts, including critics like Mr. Rothstein and proponents like Ms. McAndrew, distinguish different categories of secrecy.

There are "good faith nondisclosures," as when a floor nurse takes a phone call from someone claiming to be a family member but cannot verify that person's identity. Then there are "bad faith nondisclosures," like using Hipaa as an excuse for not taking the time to gather records that public health officials need to help child abuse investigators trying to build a case.

Most common are seat-of-the-pants decisions made by employees who feel safer saying "no" than "yes" in the face of ambiguity.

That seemed to be what happened to his own mother, Mr. Rothstein said, when she called her doctor's office

to discuss a problem. She was told by the receptionist that the doctor was not available, Mr. Rothstein said, and then inquired if the doctor was with a patient or out of the office. "I can't tell you because of Hipaa," came the reply. In fact the doctor was home sick, which would have been helpful information in deciding whether to wait for a call back or head for the emergency room.

The law, medical professionals and privacy experts said, has had the positive effect of making confidentiality a priority as the nation moves toward fully computerized, cradle-to-grave medical records.

But safeguarding electronic privacy required a tangle of regulations issued in 2003, followed last year by 101 pages of "administrative simplification."

Senator Edward M. Kennedy, Democrat of Massachusetts, a sponsor of the original insurance portability law, was dismayed by the "bizarre hodgepodge" of regulations layered onto it, several staff members said, and by the department's failure to provide "adequate guidance on what is and is not barred by the law." To that end, Mr. Kennedy, along with Senator Patrick M. Leahy, Democrat of Vermont, plans to introduce legislation creating an office within the Department of Health and Human Services dedicated to interpreting and enforcing medical privacy.

"In this electronic era it is essential to safeguard the privacy of medical records while insuring our privacy laws do not stifle the flow of information fundamental to effective health care," Mr. Kennedy said.

This spring, the department revised its Web site, www.hhs.gov/ocr/hipaa, in the interest of clarity. But Hipaa continues to baffle even the experts.

Ms. McAndrew explained some of the do's and don'ts of sharing information in a telephone interview:

Medical professionals can talk freely to family and friends, unless the patient objects. No signed authorization is necessary and the person receiving the information need not have the legal standing of, say, a health care proxy or power of attorney. As for public health authorities or those investigating crimes like child abuse, Hipaa defers to state laws, which often, though not always, require such disclosure. Medical workers may not reveal confidential information about a patient or case to reporters, but they can discuss general health issues.

Ms. McAndrew said there was no way to know how often information was withheld. Of the 27,778 privacy complaints filed since 2003, the only cases investigated, she said, were complaints filed by patients who were denied access to their own information, the one unambiguous violation of the law.

Complaints not investigated include the plights of adult children looking after their parents from afar. Experts say family members frequently hear, "I can't tell you that because of Hipaa," when they call to check on the patient's condition.

That is what happened to Nancy Banks, who drove from Bartlesville, Okla., to her mother's bedside at Town

and Country Hospital in Tampa, Fla., last week because Ms. Banks could not find out what she needed to know over the telephone.

Her 82-year-old mother had had a stroke. When Ms. Banks called her room she heard her mother "screaming and yelling and crying," but conversation was impossible. So Ms. Banks tried the nursing station.

Whoever answered the phone was not helpful, so Ms. Banks hit the road. Twenty-two hours later, she arrived at the hospital.

But more of the same awaited her. She said her mother's nurse told her that "because of the Hipaa laws I can get in trouble if I tell you anything."

In the morning, she could speak to the doctor, she was told.

The next day, Ms. Banks was finally informed that her mother had had heart failure and that her kidneys were shutting down.

"I understand privacy laws, but this has gone too far," Ms. Banks said. "I'm her daughter. This isn't right."

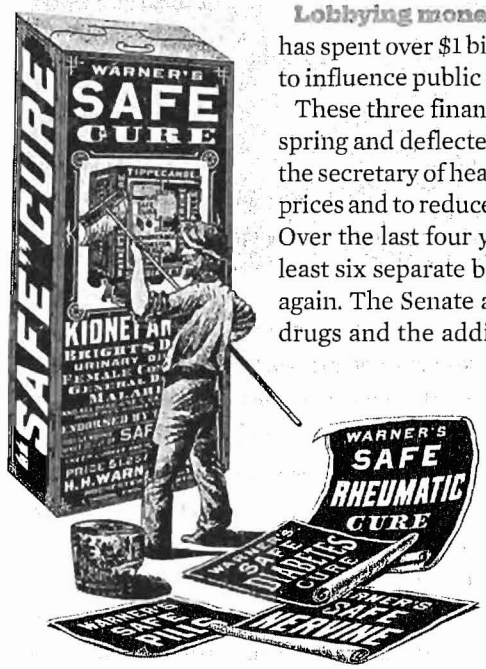
A hospital spokeswoman, Elena Mesa, was asked if nurses were following Hipaa protocol when they denied adult children information about their parents.

She could not answer the question, Ms. Mesa said, because Hipaa prevented her from such discussions with the press.

Dan Frosch contributed reporting from Denver, and Thayer Evans from Houston.

The More Things Change ...

We've come a long way from the days of Warner's Safe Cure for Diabetes. ■ Warner's was an elixir peddled at the turn of the last century, typical of a generation of potions that were heavy on promotion and light on actual benefit. After decades of debate and a timely push from Teddy Roosevelt, Congress passed the Food and Drug Act of 1906. But like that law, every effort to regulate the industry since has faced stiff resistance from the drug industry. Granted, the pharmaceutical industry has helped make the nation healthier, kept us out of hospitals and nursing homes and extended our lives. As a nation, we depend on drugmakers' research skills and creativity. Still, the industry continues to mix a potent brew of financial largess and political influence that at times has stymied public officials and overwhelmed lawmakers. ■ Let's follow the money: **Approval money.** The Food and Drug Administration expects $400 million from the drug industry to finance the approval process of brand-name drugs next year. That distorts the FDA's drug approval process by accelerating availability of high-cost drugs at the expense of a growing backlog of low-cost generics whose approval depends on scarce federal funds.



1,100 industry arm-twisters have spent over $1 billion since 1998.

Campaign money. The drug and health products industry has directed $93 million to congressional and presidential candidates since 2000, according to the nonpartisan Center for Responsive Politics.

Lobbying money. An army of 1,100 lawyers and arm-twisters has spent over $1 billion since 1998, more than any other industry, to influence public officials and shape drug legislation.

These three financial trails converged with a new Congress this spring and deflected efforts to secure greater FDA scrutiny, to let the secretary of health and human services bargain for lower drug prices and to reduce drug costs by legalizing imports from Canada. Over the last four years, industry lobbyists effectively blocked at least six separate bills approving importation. In May they did it again. The Senate also rejected a partial advertising ban for new drugs and the addition of another step to the approval process that would have added an independent voice in post-market assessments. That amendment failed by one vote. [See special reports on page 16 and at www.aarp.org/bulletin.]

The one constant in these debates was the pharmaceutical lobbying money and campaign contributions. This is not to suggest that the senators were bought off by campaign contributions. That's illegal, and it's not how the system works. But campaign contributions do provide special interests greater access to lawmakers.

And where does that leave consumers? Americans pay almost twice as much per capita for their medical care as people in other industrialized nations, yet our longevity rate is lower and our child mortality rate higher. The drugs we take are a major factor in those inflated numbers for medical care. A recent study by the management consulting firm McKinsey & Co. calculated that each American pays $728 a year for prescriptions, nearly twice the average cost for the industrial world. The pharmaceutical industry is fond of saying that as a share of the total health bill, Americans pay no more for their drugs than they did in 1960. That ignores the fact that the cost of health care today is three times what it was in 1960.

Warner's Safe Cure is long gone—except at antique shows. It was banned in the 1930s. In its wake are higher prices and a regulatory system that is vastly underfinanced and overwhelmed and remains too close to the pharmaceutical industry it is supposed to regulate. —The Editors

Public Ed

FDA Office of Public Affairs
<FDAOPA@FDA.HHS.GOV>
Sent by: FDA press releases and announcements
<FDANEWSWIRE@list.nih.gov>

06/21/2007 07:05 AM

Please respond to
FDA Office of Public Affairs
<FDAOPA@FDA.HHS.GOV>

To FDANEWSWIRE@list.nih.gov
cc
bcc
Subject FDA News Release: FDA Clears 'Computerized Medication Box' for U.S. Market

FDA NEWS RELEASE

For Immediate Release: June 21, 2007

Release No. P07-106

Media Inquiries: Kris Mejia, 301-827-6242, kristine.mejia@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Clears 'Computerized Medication Box' for U.S. Market

The U.S. Food and Drug Administration has cleared for marketing the INRange Systems' Electronic Medication Management Assistant (EMMA), a programmable device that stores and dispenses prescription medication for patients' use in the home.

Essentially a computerized medication box, EMMA was designed to be used under the supervision of a licensed health care provider. EMMA can reduce drug identification and dosing errors, and allow health care professionals to monitor patient adherence to medication regimens in an outpatient setting. It may be especially useful for aging patients, as well as those with complex medication regimens such as patients with HIV.

"FDA's clearance of the INRange remote medication management system puts an important safety tool directly in the hands of patients and their health care providers," said Daniel Schultz, M.D., director of FDA's Center for Devices and Radiological Health. "It will help take away some of the confusion patients can experience when taking prescription medications, and allow care providers to more closely monitor their patients' medications between office visits."

A 2006 Institute of Medicine report estimated that medication errors harm at least 1.5 million people in the United States annually.

EMMA consists of a medication delivery unit and two-way communication software that allows a health care professional to remotely manage prescriptions stored and released by the patient-operated delivery unit. The delivery unit is about the size of a bread box and plugs into a standard power outlet.

EMMA stores prescription medications, emits an audible alert to the patient when the prescribed medications are scheduled to be taken, and releases them onto a delivery tray when activated by the patient at the appropriate time. It uses a Web-based application for a health care professional, such as a doctor or pharmacist, to remotely schedule or adjust a patient's prescribed medications,

and provides the health care professional with a history of each time patients access their medications.

FDA reviewed safety and effectiveness information for EMMA under the "*de novo*" classification process. The ability to petition for "de novo" initial classification was added under the Food and Drug Administration Modernization Act of 1997 to establish an additional way for novel, but less risky, devices to get to market.

The EMMA system is manufactured by INRange Systems based in Altoona, Pa.

#

Public Ed

FDA Change on RPh Drug Class?

In a reversal of long-standing opposition, the Food and Drug Administration (FDA) has suggested that it might be time to establish a behind-the-counter class of non-prescription drugs.

FDA Commissioner Andrew von Eschenbach, MD, described products that could be included in the potential pharmacy drug class as "medications that can be available without the need for a prescription by a health care professional, but are delivered in the context of being able to have patients guided and directed and instructed about their appropriate use," according to an account in *Health News Daily*. He also indicated that he wasn't sure FDA had the regulatory authority to establish a class somewhere between Rx and OTC, or whether legislation would be required.

The locale for von Eschenbach's remarks was significant. They were made at the annual conference of the Consumer Healthcare Products Association (CHPA), the OTC industry lobby, which historically has been hostile to a "third class" of drugs by any name. The NCPA staff has been in discussions with FDA since to determine exactly what von Eschenbach has in mind.

Because of rapid developments in the Rx-to-OTC reclassification arena, such as Plan B being switched and the attempted switch of Mevacor, and in light of the fact that the pharmacist is a primary guardian of the public health, NCPA believes it is time to reexamine a "pharmacist legend" class of drugs.

In 1984, NCPA developed this concept and submitted it to the FDA, which rejected it. NCPA argued at the time that a pharmacist legend interim stage of drug distribution would reduce consumer health care costs, increase convenience, and provide a vehicle for postmarket safety supervision for consumer protection. Our proposal would not have changed the status of drugs that currently were OTC, nor remove any from Rx-only. NCPA does not believe pharmacist legend is synonymous with a "third class of drugs," but instead an interim stage of drug marketing for appropriate drugs being switched from prescription to OTC status.

The third class of drugs concept is a fixed category. Under NCPA's approach, a switched drug would remain in the new drug category only for as long as it takes the FDA to determine if there is imminent risk to the public health if it were to be released to non-pharmacy outlets.

"It was a good idea at the time," said Bruce Roberts, RPh, NCPA executive vice president and CEO, "and one that should be looked at again under any name."

CMS Announces NPI Contingency Plan

The Centers for Medicare & Medicaid Services (CMS) has announced that it will not impose penalties on covered entities, including pharmacies and health plans, for non-compliance with the National Provider Identifier (NPI) requirement provided a good faith effort and contingency plan are made to comply with the requirement.

This announcement related to penalties does not mean that there is

Continued on page

DRUG TOPICS
150 Years of Dedication to Pharmacy

Public ed

Verispan takes a past and future look at drug market

Verispan takes a past and future look at drug market

Aug 24, 2007
Drug Topics Daily News

Three developments will have a major impact on the pharmaceutical market going forward. That's the assessment of Tara Hamm, an analyst with market research firm Verispan. Hamm gave an update on the market at *Drug Topics'* Advanstar headquarters in Woodcliff Lake, N.J., on Aug. 22. The three developments she cited include:

- potentially significant government influence over health care, with the upcoming Presidential election
- the growth of e-prescribing
- the proliferation of retail-based health clinics

Then taking a look back at the market, Hamm told the audience:

- The average price for generics rose just 5 cents per unit over the past six years. In contrast, branded products rose by an average of 99 cents per unit over the same period.
- From 2000 to 2007, only 163 new molecular entities (NMEs) were approved, whereas in the seven years before 2000, 232 NMEs received the green light.

To see more Hot off the Press news articles, click here.

To go to the *Drug Topics* homepage, click here.

FDA U.S. Food and Drug Administration
U.S. Department of Health and Human Services

Public Ed

FDA News

Media Inquiries:
Michael Herndon
Kimberly Rawlings
301-827-6242
Consumer Inquiries:
888-INFO-FDA

FOR IMMEDIATE RELEASE
June 22, 2007

FDA Issues Dietary Supplements Final Rule

The U.S. Food and Drug Administration today announced a final rule establishing regulations to require current good manufacturing practices (cGMP) for dietary supplements. The rule ensures that dietary supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled.

"This rule helps to ensure the quality of dietary supplements so that consumers can be confident that the products they purchase contain what is on the label," said Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D. "In addition, as a result of recent amendments to the Federal Food, Drug, and Cosmetic Act, by the end of the year, industry will be required to report all serious dietary supplement related adverse events to FDA."

The regulations establish the cGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and the finished product. It also includes requirements for recordkeeping and handling consumer product complaints.

"The final rule will help ensure that dietary supplements are manufactured with controls that result in a consistent product free of contamination, with accurate labeling," said Robert E. Brackett, Ph.D., director of FDA's Center for Food Safety and Applied Nutrition.

Under the final rule, manufacturers are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or do not contain the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

The aim of the final rule is to prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, contamination by substances such as natural toxins, bacteria, pesticides, glass, lead and other heavy metals, as well as improper packaging and labeling.

The final rule includes flexible requirements that can evolve with improvements in scientific methods used for verifying identity, purity strength, and composition of dietary supplements.

As a companion document, FDA also is issuing an interim final rule that outlines a petition process for manufacturers to request an exemption to the cGMP requirement for 100 percent identity testing of specific dietary ingredients used in the processing of dietary supplements.

Under the interim final rule the manufacturer may be exempted from the dietary ingredient identity testing requirement if it can provide sufficient documentation that the reduced frequency of testing requested would still ensure the identity of the dietary ingredient. FDA is soliciting comment from the public on the interim final rule. There will be a 90-day comment period, ending on September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at www.fda.gov/dockets/ecomments.

The final CGMP and the interim final rule are effective August 24, 2007. To limit any disruption for dietary supplements produced by small businesses, the rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008 to comply, companies with less than 500 employees have until June 2009 to comply, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

Backgrounder: http://www.cfsan.fda.gov/~dms/dscgmps7.html

Fact Sheet: http://www.cfsan.fda.gov/~dms/dscgmps6.html

To see a consumer article called "Final Rule Promotes Safe Use of Dietary Supplements," visit http://www.fda.gov/consumer/updates/dietarysupps062207.html.

####

RSS Feed for FDA News Releases [what is RSS?]

Agenda Item 8

Update on the Board's Public Outreach Activities

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

September 7, 2007

To: Communication and Public Education Committee

Subject: Update on the Board's Public Outreach Activities

Public and licensee outreach activities performed since the June report to the committee include:

- Board Member Goldenberg provided information about the board's citation and fine program to the Pharmacists Professional Society of San Fernando Valley on June 24.
- Board Member Ravnan provided information about medication errors as part of panel discussion with Lyle Bootman and Michael Cohen hosted by *Drug Topics* in concert with the American Society of Health Systems Pharmacists annual meeting in San Francisco on June 26.
- Supervising Inspector Nurse met with visiting dignitaries from Australia who were interested in learning about California's controlled substances requirements.
- Supervising Inspector Judi Nurse provided information about the Veterinary Food Animal Drug Retailer program to a group of food animal veterinarians on August 23.
- Public Outreach Coordinator Karen Abbe staffed an information booth for the Department of Consumer Affairs and the board at the California State Fair on August 31.

Future:

- Supervising Inspector Ming will provide information about pharmacy law to the Indian Pharmacist Association on September 15.
- Supervising Inspector Nurse will speak about California's pedigree requirements at LogiPharma's annual conference in Philadelphia on September 17.
- Analyst Sue Durst will staff an information booth on September 17 at the Senior Fraud Fest event at the South San Francisco Conference Center.
- The board will host an information booth at a health fair at the Siskiyou County Fairgrounds on September 22.
- Executive Officer Herold and AG Liaison Room will speak at the Healthcare Distribution Management Association's two-day conference, California Pedigree: Preparing for Implementation on September 27.
- Executive Officer Herold and Supervising Inspector Nurse will speak at EPCglobal's annual US Exposition on California's pedigree requirements in Chicago on October 3.

- President Powers will speak to the Renaissance Society (a group of seniors) on October 5 about purchasing drugs online and other consumer issues involving pharmacy.
- Public Outreach Coordinator Abbe will staff a booth at the 22nd Annual Marin County Senior Information Fair on October 10.
- Executive Officer Herold and Supervising Inspector Nurse will speak about California's electronic pedigree requirements along with EPCglobal at CSHP's Seminar on October 20 in Palm Springs.
- The board will staff an information booth at the CSHP's Seminar on October 19 and 20.
- Board Member Goldenberg will provide a presentation on the board's citation and fine program to pharmacists attending a USC continuing education program on January 26, 2008 in Ojai.
- Ken Schell will provide information on the board's compounding requirements at CPhA's annual meeting in February 2008.